ATTACHMENT 1

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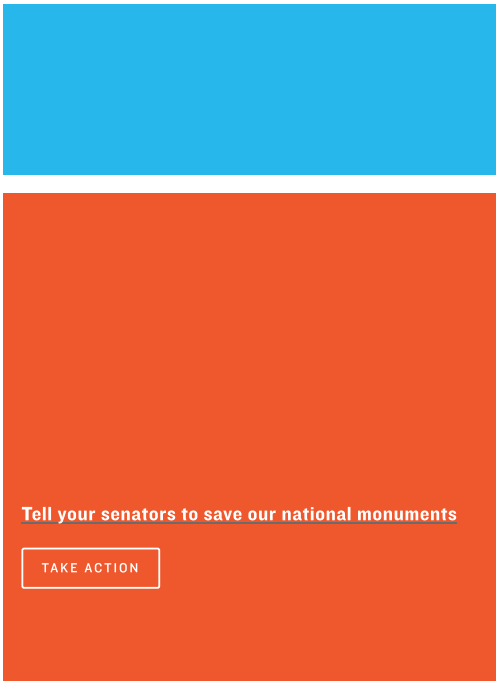

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We combine the expertise of nearly 500 scientists, lawyers, and advocates with the power of more than two million activists to confront our planet's most pressing problems.

- **Offshore Drilling in the Atlantic? "That's Not Who We Are."**

  Southern communities prefer their coastlines sandy, beautiful, and bountiful—not filled with rigs and air guns blasting ships or covered in oil.

- **Banishing the Climate Change Blues**

  Anxious about where our planet is headed? Tip one: You're not alone—and that means a lot.

- **When Clean Water's Not Clear**

  The Trump administration wants to open our waterways back up to pollution.

- **The Undeniable, Commonsense Response to Harvey**

  We must fight climate change today in order to protect people from such disasters tomorrow.

- **Our Public Lands and Waters Belong to You and Me**

  For the first time in America's history, many of our national monuments are at risk for industrial exploitation.

- **Fighting the Trump Agenda: A Step-by-Step Guide**

  Tracking Trump's attacks on the environment and how you can help NRDC stop him.

- **Is America Actually Out of the Paris Agreement?**

  The agreement's authors built in a time line for withdrawal that President Trump will have to follow—slowing him down from irreparably damaging our climate.

- **This Harmful Pesticide Should Have Been Banned Years Ago. Now It Could Finally Happen.**

  Thankfully, senators are stepping in where Donald Trump's EPA has fallen down.

- **Trump Watch**

  NRDC tracks the Trump administration's assaults on the environment.

- **Offshore Drilling in the Atlantic? "That's Not Who We Are."**

  Southern communities prefer their coastlines sandy, beautiful, and bountiful—not filled with rigs and air guns blasting ships or covered in oil.

- **Banishing the Climate Change Blues**

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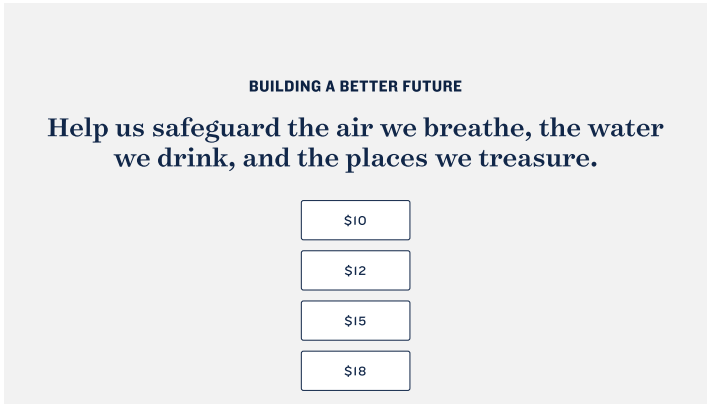

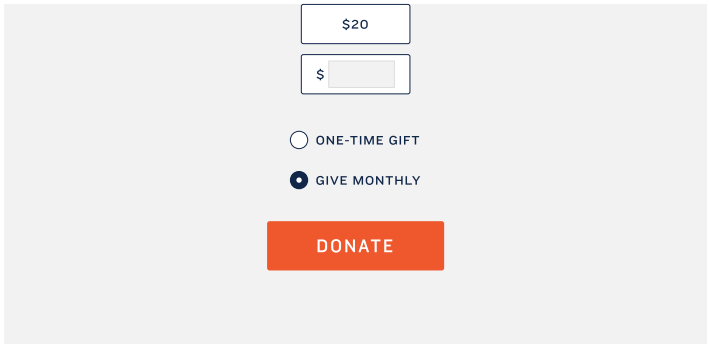

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NRDC (Natural Resources Defense Council)
August 25 at 12:24pm ·

Secretary Zinke is trying to keep the Interior Department's report on national monuments a secret. So we filed a FOIA request.

“We call on Secretary Zinke to stop hiding from the public." - Rhea Suh, NRDC president

Read our statement on today's Freedom of Information Act request: on.nrdc.org/2wNYfxZ... See More

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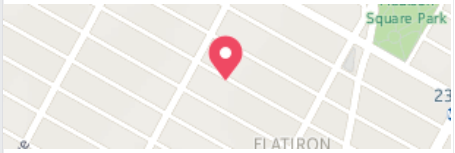

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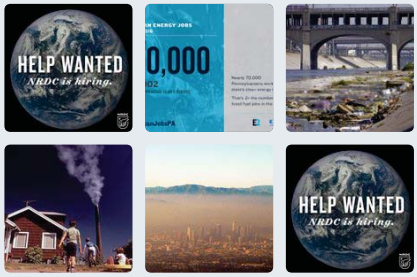

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NRDC @NRDC · Sep 8
This year's hurricane season is showing us the folly of planning for infrastructure without planning for flooding.

Irma? Harvey?—We Need to Talk About Infrastructure. Now.
But if we don't discuss flood protection, too, it's meaningless.
nrdc.org

4 112 168

NRDC @NRDC · 28m
Nearly 70,000 Pennsylvanians work in the clean energy sector—that's 2x the number of fossil fuel jobs in the state.

Clean Jobs Pennsylvania 2017 - Environmental Ent…
Report There are nearly 70,000 clean energy jobs in Pennsylvania, according to a new report released in August 2017 by E2 and our partners at the Keystone...
e2.org

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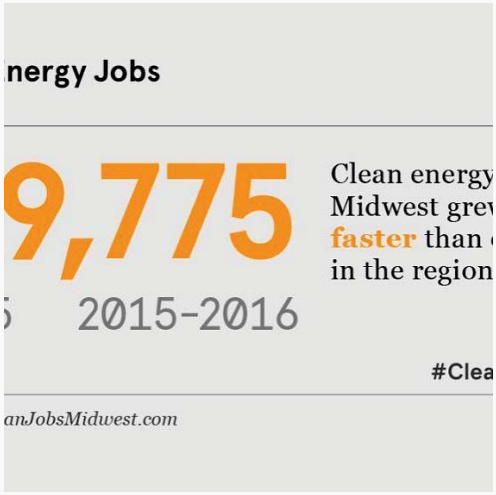
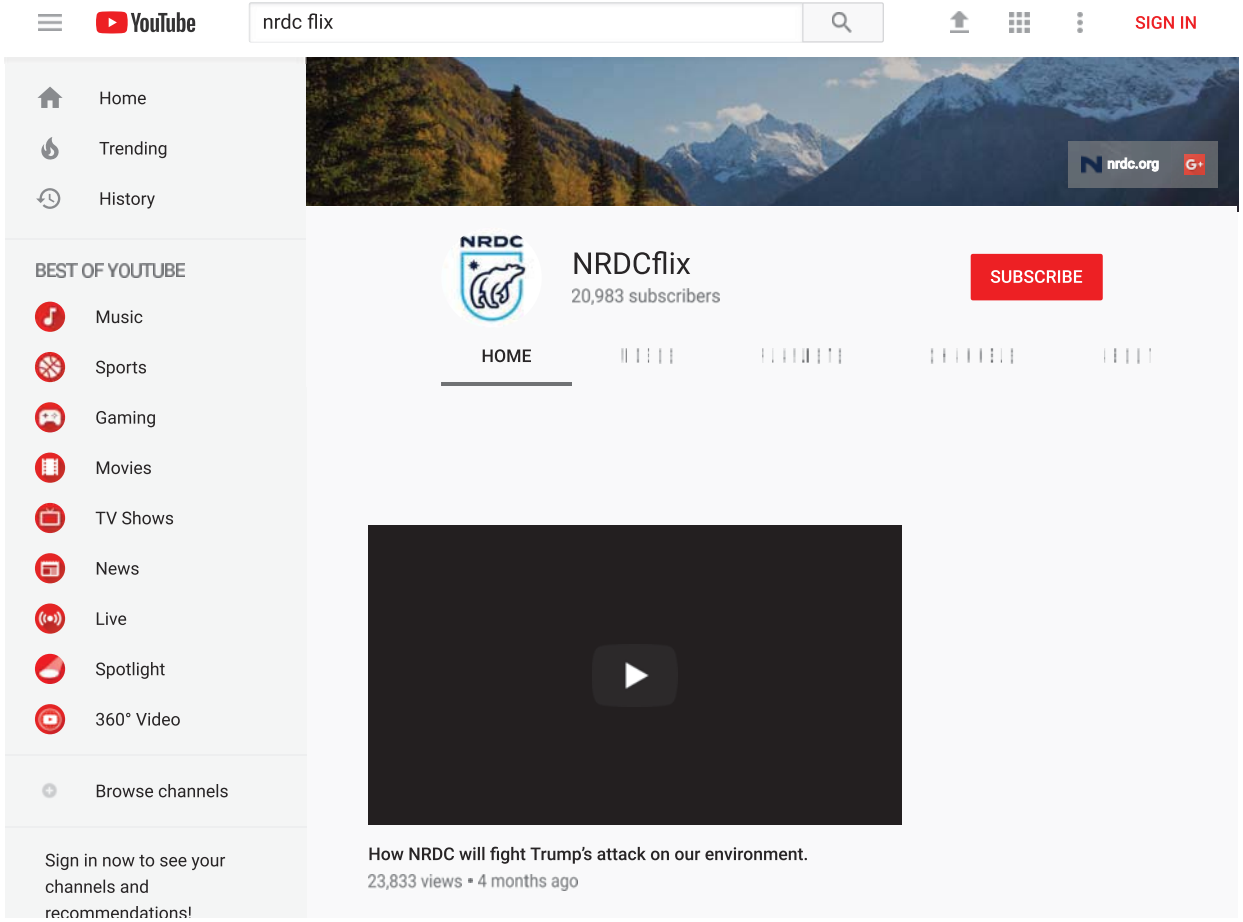


ATTACHMENT 5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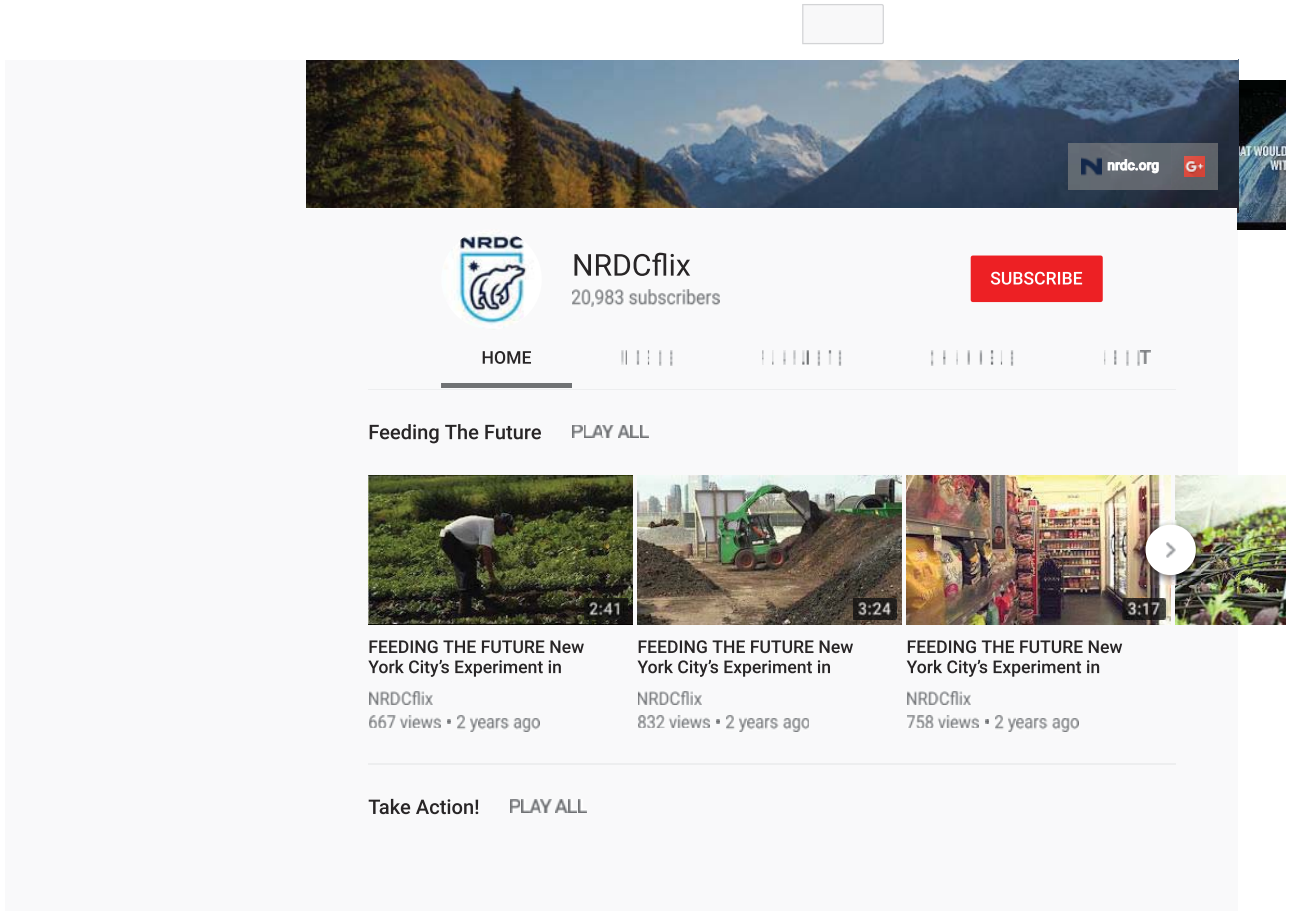
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NRDC is the nation's most effective environmental action organization. We use law, science and the support of 1.3 million members and online activists to protect the planet's wildlife and wild places and to ensure a safe and healthy environment for all living things.

Worth Magazine has named NRDC one of America's 100 best charities, and the Wise Giving Alliance of the Better Business Bureau reports that NRDC meets its highest standards for accountability and use of donor funds.

NRDC was founded in 1970 by a group of law students and attorneys at the forefront of the environmental movement. NRDC lawyers helped write some of America's bedrock environmental laws. Today, our staff of more than 300 lawyers, scientists and policy experts -- a MacArthur "genius" award-winner among them -- work out of offices in New York, Washington, Chicago, Los Angeles, San Francisco and Beijing.

The New York Times calls us "One of the nation's most powerful environmental groups." The National Journal says we're "A credible and forceful advocate for stringent environmental protection."

With the support of our members and online activists, NRDC works to solve the most pressing environmental issues we face today: curbing global warming, getting toxic chemicals out of the environment, moving America beyond oil, reviving our oceans, saving wildlife and wild places, and helping China go green.

Website
http://www.nrdc.org

Industry
Environmental Services

Type
Non Profit

Company Size
201-500 employees

Founded
1970

Recent Updates

Natural Resources Defense Council Current federal policies have created an unsustainable flood > rebuild > repeat cycle. Obviously, that's not working. So we're urging the Trump administration and Congress to take these 4 actions to protect the American people from future disasters.

The Nation's Approach to Managing Flood Risks Must Change

nrdc.org • In the era of climate change, the "business-as-usual" approach for addressing flooding is no longer an option. Current federal policies create an unsustainable "flood, rebuild, repeat" situation for managing the nation's flood risks.

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Natural Resources Defense Council Become a force for nature! E2 is hiring an Eastern States Advocate to fill a critical role on its growing team in NRDC's NYC office. NRDC's Environmental Entrepreneurs (E2) program is the business voice for the environment. Apply now: http://on.nrdc.org/2j1RIua

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Natural Resources Defense Council Lawmakers in California are considering a revolutionary bill that would aim to create a fossil fuel free grid by 2045 in the state. Hopefully, this plan will start a wave of green cooperation across the entire US!

California is considering a mandate to make the state's entire grid fossil fuel free

futurism.com • This would ideally cause a chain reaction leading to a nation of green cooperation, from sea to shining sea.

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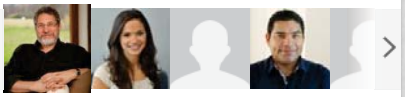

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ATTACHMENT 7

Telfer, Kathleen

From: NRDC - Rhea Suh <alerts@nrdcaction.org>
Sent: Thursday, September 14, 2017 4:15 PM
To: Telfer, Kathleen
Subject: Pruitt doesn't want to talk climate -- so we will

Dear Kathleen–

The science indicates that Hurricanes Irma and Harvey were almost certainly made more powerful and destructive by climate change. These storms, along with the record heat and raging wildfires in the West, are calling out for real solutions to climate change.

EPA chief Scott Pruitt says he doesn't believe we should be talking about climate change now. No surprise, given Pruitt's and President Trump's climate denial and their efforts to roll back climate action.

But attitudes are shifting — including among Republicans. As Tomás Regalado, Republican mayor of Miami, FL — a city battered by Irma — countered: *"This is the time that the president and the EPA and whoever makes decisions needs to talk about climate change."*

And Senator John McCain told CNN this week that it was time to sit down and discuss potential solutions to climate change.

Let's use Mayor Regalado's and Senator McCain's bipartisan call to arms to pressure Democrats and Republicans to renounce climate denial and embrace climate action. ***Take action or find out more below.***

Thanks for your support.

Kathleen,

It's been 11 days since Hurricane Harvey struck Texas, and now many Caribbean islands and Florida and other southeastern states face a new potentially devastating hurricane with Irma.

The nation is focused — as we should be — on recovery and rebuilding in the wake of Harvey, and all-important preparations for this new storm racing toward us.

But looming large over these storms is an issue that we ignore at our own peril: climate change.

No climate scientist would pin all the blame for any one hurricane or any one extreme weather event on climate change.

With Harvey and Irma, Help Turn Disaster Into Climate Action

Send leaders a last-chance wake-up call: Hurricanes Harvey and Irma are a turning point in America's fight for climate solutions.

TAKE ACTION

But we do know this: climate change almost certainly made Harvey more devastating. The Gulf of Mexico's waters are at record warmth. And warmer waters and air fuel more powerful and destructive storms.

Only the willfully blind can ignore the larger pattern of extreme weather: Harvey is the third 500-year storm — or worse — to hit Houston in just three years. It is just the latest in a string of catastrophic floods and storm events to strike the nation. Across America and around the world heat waves and rainstorms are growing more intense — just as climate scientists have predicted for decades.

At this point, climate change is *screaming* for our attention. But President Trump and congressional leaders have got their fingers in their ears, pretending that all will be well if only we would agree to deny climate science.

That aversion to science is looking more and more like an invitation to a rolling planet-wide catastrophe. We've seen the future and it looks a lot like Houston.

So, please send our leaders a wake-up call: Hurricanes Harvey and Irma must be

the turning point in America's willingness to tackle climate change and aggressively pursue a clean energy future.

We'll send your message to President Trump, Vice President Pence, cabinet officials, Congress, and your governor and state representatives, all of whom must act now and must know that we are watching them.

The fossil fuel industry still has a financial stranglehold on far too many politicians. Here's the evidence:

- President Trump's proposed federal budget — which is now being negotiated by Congress — seeks to abolish nearly every climate change program on the books at the EPA, Department of Energy, and other key agencies.
- Agency officials like the EPA's Scott Pruitt are ignoring — or driving out — scientists we urgently need working on climate change and clean energy.
- The Trump administration is pulling America out of the Paris climate agreement and trying to dismantle the Clean Power Plan — our single best hope for speeding up the transition away from coal and other dirty fossil fuels.
- And the administration is ramping up efforts to drill for more oil and gas in the Arctic, off our coasts, and even in our cherished national monuments.

These attacks must stop, and after Hurricane Harvey, **we must demand that President Trump, Congress, and even state and local leaders get serious about tackling climate change before it's too late**.

But make no mistake: we must do *more* than cut global warming pollution. Burning of fossil fuels has already locked us into more climate change — *and more extreme weather*. **So it's absolutely crucial that, in the wake of Hurricane Harvey and with Irma approaching, we clean up and rebuild in a way that protects millions of people in vulnerable areas from future storms.**

That's why NRDC and the NRDC Action Fund are working closely with our partners in the Gulf region and around the country to address the recurring problems of flooding from record storms and sea level rise ... the toxic mess left behind by flooded petrochemical plants ... fighting back in Washington against short-sighted cuts to FEMA, the National Weather Service, NOAA, and other agencies that better prepare us for the impacts of climate change.

And right now, we are pushing to fix the fatally flawed federal flood insurance

program that continues to subsidize building in flood-prone areas. And we're working to reverse President Trump's decision, just days before Harvey hit, to abolish federal flood standards meant to protect people and property from storms like this.

In the days and weeks ahead, we will call on members and supporters like you to ratchet up the pressure on political leaders to abandon policies that are making natural disasters like Hurricane Harvey even worse, and to win new, smarter policies that will better protect all Americans.

But for now, please seize this moment to send a message demanding strong action on climate — for the sake of every person on this planet.

Sincerely,

Rhea Suh
President, NRDC

The mission of the Natural Resources Defense Council (NRDC) is to safeguard the Earth: its people, its plants and animals, and the natural systems on which all life depends.

We appreciate the opportunity to communicate with you and other NRDC Activists. We are committed to protecting your privacy and will never sell, exchange or rent your email address.

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ATTACHMENT 8

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Whether you want to fight against Big Coal or for struggling species, adding your voice

will make a difference.

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Stop Trump and Pruitt's escalated anti-environment assault

ATTACHMENT 9

Natural Resources Defense Council

Protecting our land, air, and water since 1970.

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California: America's Climate Leader

The Golden State is stepping up its game to set the standard for powering our nation through 100 percent clean, renewable energy.

Rhea Suh
Sep 11

ATTACHMENT 10

Henry Henderson

Natural Resources Defense Council Midwest Program Director

Henry Henderson is the director of NRDC's Midwest office, which opened in Chicago in 2007. He was the founding commissioner for the City of Chicago's Department of Environment from 1992 to 1998, and served as the Illinois assistant attorney general from 1985 to 1987. As commissioner, he developed an environmental mission for the city, which included the development of the Chicago Brownfield Initiative, a natural resources rehabilitation initiative, the city's energy policies and utility regulations, and Chicago's clean air initiative to improve regional air quality while promoting economic development. He has taught environmental law and policy at the University of Chicago and the University of Illinois at Chicago. He blogs on NRDC's Switchboard.

A Year After Report, Flint Lacks Federal Aid and Safe Water

Congressional Hearings Should Reflect That Flint Is Not Fixed

Tests (or Lack Thereof) Show New Players Needed to Fix Flint

Flint Still Flubbed — More Answers, Accountability and Action Needed in Michigan

It's Prime Time For Ohio To Embrace Better Wind Energy Policies

EPA Flakes on Flint

ATTACHMENT 11

NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

Arsenic and Old Laws

A Scientific and Public Health Analysis of Arsenic Occurrence in Drinking Water, Its Health Effects, and EPA's Outdated Arsenic Tap Water Standard

---

This February 2000 report analyzes data collected by water systems in 25 states between 1980 and 1998 and compiled by the U.S. Environmental Protection Agency. The study finds that millions of Americans drink tap water from systems that have been shown to contain arsenic, a known toxin and carcinogen, at average levels that pose unacceptable cancer risks. This report includes a summary of the adverse health effects of arsenic in drinking water by Dr. Paul Mushak, an eminent expert on the subject, based upon a 1999 National Academy of Sciences report. The report also contains detailed recommendations on what the EPA and water systems should do to reduce arsenic in drinking water and safeguard the health of the American public.

TABLE OF CONTENTS

Check the map

For an overview of the geographic distribution of arsenic problems in 25 states

For printed copies of this report, see our Publications List.

Related NRDC Pages
FAQ

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NATURAL RESOURCES DEFENSE COUNCIL

Arsenic and Old Laws

A Scientific and Public Health Analysis of Arsenic Occurrence in Drinking Water, Its Health Effects, and EPA's Outdated Arsenic Tap Water Standard

Top of Report

EXECUTIVE SUMMARY AND RECOMMENDATIONS

FINDINGS

Arsenic in drinking water poses a significant public health risk in the United States. According to our most conservative analysis of new EPA data covering only 25 states, at least 34 million Americans in over 6,900 communities drank tap water supplied by systems containing arsenic, a known toxin and carcinogen, at average levels that pose unacceptable cancer risks.[1] Our "best" estimate, based on what we believe to be the most reasonable (but less conservative) analytical techniques, indicates that 56 million Americans in over 8,000 communities in those 25 states drank water with arsenic at these risky levels.[2]

These newly public figures are based on more than 100,000 arsenic samples collected from 1980 to 1998 by more than 24,000 public water systems in 25 states, which were then compiled by the U.S. Environmental Protection Agency (EPA). The Natural Resources Defense Council (NRDC) obtained the data under the Freedom of Information Act and analyzed them. While arsenic levels can vary with time, when considering cancer risk, the average levels generally are of primary concern. For this reason, NRDC calculated average arsenic levels in the systems evaluated. Because data were available for only half of the states in the nation, these are likely to be significant underestimates of the total U.S. population exposed to arsenic in tap water.

NRDC also has generated maps for this report showing the geographic distribution of arsenic problems for all 25 reporting states. This marks the first time that EPA□s drinking water database has been publicly analyzed using a Geographic Information System (GIS) to generate maps of drinking water problems.

This report includes a summary of the adverse health effects of arsenic in drinking water by an eminent expert on the subject, based upon a 1999 National Academy of Sciences (NAS) report and a review of peer-reviewed literature. The NAS report and other scientific literature discussed here have concluded that arsenic in drinking water is a known cause of bladder, lung, and skin cancer. In addition, the NAS report and many previous studies have found that arsenic in drinking water may also cause kidney and liver cancer.

Arsenic□s known noncancer toxic effects include toxicity to the central and peripheral nervous systems, heart and blood vessel problems, and various precancerous lesions on the skin, such as hyperkeratosis (a pronounced scaly skin condition) as well as changes in pigmentation. The NAS report and peer-reviewed animal studies have found that arsenic may also cause birth defects and reproductive and other problems, although some of these effects are less documented than arsenic's cancerous, skin, nervous, and cardiovascular effects.

The NAS concluded in 1999 that EPA□s 57 year-old arsenic standard for drinking water of 50 parts per billion (ppb), set in 1942 before arsenic was known to cause cancer, "does not achieve EPA□s goal for public health protection and, therefore, requires downward revision as promptly as possible" (NAS, 1999, p. 9). In fact, the academy said that drinking water at the current EPA standard "could easily" result in a total fatal cancer risk of 1 in 100 -- about a 10,000 times higher cancer risk than EPA would allow for carcinogens in food, for example.

RECOMMENDATIONS

- **EPA must immediately adopt a strict, health-protective standard for arsenic in tap water.** The Safe Drinking Water Act (SDWA) Amendments of 1996 required EPA to propose a revised arsenic standard (to replace the old standard set in 1942) by January 1, 2000, a deadline the agency has missed. This is the third time EPA has violated a statutory mandate to update the arsenic standard. EPA is required to finalize a new standard by January 1, 2001. We conclude -- as did NAS -- that EPA should expeditiously issue a stricter Maximum Contaminant Level standard for arsenic. EPA must consider that many Americans also have unavoidable exposure to arsenic in their food, so relatively low levels of arsenic in tap water can cause safety levels to be exceeded. A health-protective tap water arsenic standard should allow a maximum lifetime cancer risk no greater than that EPA has traditionally accepted (a level presenting a lifetime cancer risk from 1 in 1,000,000 to at most 1 in 10,000 for vulnerable or highly exposed individuals).

  This would require EPA to set a drinking water standard well below the current 50 ppb standard -- in the range of 1 ppb. Limitations in the analytical techniques widely used for measuring arsenic in water, however, would likely necessitate a standard of 3 ppb, rather than a standard of 1 ppb, because reliably quantifying arsenic at levels below this would be difficult using current standard lab equipment and practices.

said probably overestimate costs, indicate that the cost per household of a 2 ppb standard would be from $5 to $14 per month for the vast majority (87 percent) of affected consumers; users of small systems may have to pay significantly more. EPA□s (admittedly high) estimates also project that nationally an arsenic standard of 2 ppb would cost $2.1 billion per year, and a 5 ppb standard would cost $686 million per year.

- **EPA should reduce its cross-media guidance level for arsenic and should fund improved analytical methods to lower detection limits for arsenic.** Health data indicate that EPA's current guidance level establishing the maximum recommended daily arsenic exposure, called a reference dose (which is unenforceable itself, but is used by EPA in developing enforceable standards in all environmental media, including water), is too high and may not protect vulnerable populations, such as children. To protect children, EPA should reduce this reference dose from 0.3 micrograms per kilogram per day (µg-kg per day) to at most 0.1 µg-kg per day, and should immediately reevaluate the reference dose in light of the 1999 NAS risk estimates, suggesting that the cancer risk at this level would still be unacceptable. In addition, EPA should fund efforts to reduce the level at which arsenic can be reliably detected in drinking water, so that it can be found down to levels at which it may pose a health risk (below 1 ppb).

- **Water systems should be honest with their customers about arsenic contamination and potential health risks.** Only if water systems tell their customers the truth about arsenic contamination in their tap water, and about the health threat it poses, will the public support efforts (including possible rate increases) to remedy the problem.

- **Systems with arsenic problems should work with government officials to clean up their source water.** Some systems may be able to reduce arsenic levels by cleaning up or changing the source of their water. For example, some arsenic contamination results from leaching of arsenic from old waste dumps, mines, or tailings, or from past use of arsenic-containing pesticides. Government officials and water systems should team up with citizens to remedy contamination at these sites so water supplies are not arsenic-contaminated. In addition, recent studies have shown that high groundwater pumping rates have increased arsenic levels in some wells. It should be investigated whether reducing pumping rates or reworking wells can reduce some systems□ arsenic levels.

- **Water systems unable to get cleaner source water should treat to remove arsenic; state and federal funds should be increased to assist smaller Systems in paying for upgrades.** As noted above, there is readily available treatment technology that can remove arsenic from tap water, at a cost of about $5 to $14 per month per household for the vast majority of people (87 percent) served by systems with arsenic problems. Very small systems serving a small fraction of the population drinking arsenic-contaminated water, however, will often be more expensive to clean up per household (due to the lack of economies of scale). For these systems, federal and state assistance to improve treatment is available, and arsenic contamination should be a high priority for these drinking water funds. Additional federal and state funding through State Revolving Fund (SRF), USDA's Rural Utility Service, and other programs may also be needed. The SRF established by the SDWA Amendments of 1996 should be funded at least to the full authorized amount ($1 billion per year) to help smaller systems with arsenic problems.

- **EPA should improve its arsenic and other drinking water databases.** EPA should upgrade its drinking water database, known as the Safe Drinking Water Information System (SDWIS) so that it includes all of these arsenic data, as well as unregulated contaminant data, as required by the Safe Drinking Water Act -- and makes them accessible to the public. The SDWIS database must also be upgraded to include more accurate latitude and longitude ("lat-long") data. The ready availability and low cost of new GPS (global positioning system) units for recording lat-long coordinates -- available for a few hundred dollars -- should drive EPA to require accurate lat-long data for the distribution systems, treatment plants, and intakes of each public water system. Such data will have a wealth of uses for water systems, state and local officials, EPA, and the public in using GIS systems for protecting source water, for developing targeted and well-documented rules, and for other purposes.

Notes

1. The phrase "unacceptable cancer risk" is used here to mean water containing arsenic at a level posing a lifetime risk of dying from cancers in all internal organs -- bladder, kidney, liver, and lung -- of over 1 in 10,000, based on the methodologies, estimates, and cancer risk characterizations described in the National Academy of Sciences□ recent report, *Arsenic in Drinking Water*, at 8, 301 (1999), and based on the standard assumption that a person consumes two liters of water per day. A 1 in 10,000 cancer risk traditionally is the highest cancer risk EPA ever allows in tap water when setting standards, although the agency usually seeks to set standards at a stricter level, posing a lower cancer risk. See Chapters 1 and 2 for details.

2. As discussed in Chapter 1, the 56 million population exposed figure is our best estimate of the average arsenic exposure levels of consumers in the 25 states included in the new EPA database analyzed in this report. While this analysis is conservative (it may underestimate the extent of exposure), an even more conservative analysis would suggest that a minimum of 34 million people in these 25 states drank water posing a significant cancer risk. The latter highly conservative low average estimate assumes, when calculating average arsenic levels, that no arsenic was in the water at times when early crude tests with a high reporting limit of, for example, 10 ppb, found none, even though subsequent more sensitive tests found arsenic. On the other hand, the mid-average approach assumes that arsenic

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Chapter 1
ARSENIC HAS BEEN FOUND AT LEVELS OF HEALTH CONCERN IN THE TAP WATER OF TENS OF MILLIONS OF AMERICANS IN 25 STATES

NRDC has obtained new data showing that tens of millions of Americans are consuming tap water every day that poses unacceptable cancer risks. This chapter summarizes these new arsenic occurrence data, while subsequent chapters discuss in detail the health implications of arsenic contamination of drinking water and the need for a stricter standard for arsenic in tap water.

The source of these new data is an EPA database not previously made public, obtained by NRDC under the Freedom of Information Act. In preparing to develop an updated standard for arsenic in drinking water, EPA asked all states for data on the occurrence of arsenic in the tap water served by public water systems. Twenty-five states responded (see Figure 1, National Arsenic Occurrence Map), providing over 100,000 arsenic test results taken from 1980 to 1998 from over 23,000 public water systems. These water systems serve a total of about 99.5 million Americans, or 40 percent of the 1990 U.S. population. Because the database does not cover states in which approximately 60 percent of the U.S. population resides, the estimates of population affected by arsenic in their tap water likely are substantial underestimates. NRDC has deleted from consideration, as potentially unreliable, samples that exceeded 1,000 parts per billion.

These new data reveal startling new details about the extent of arsenic contamination in the tap water. Table 1 shows our best estimate is that over 56 million Americans in these 25 states consumed water from systems containing arsenic at levels presenting a potentially fatal cancer risk above the level that is EPA□s highest acceptable cancer risk (1 in 10,000). Even our extremely conservative "low average" analysis approach indicates that at a minimum, over 34 million people in these 25 states drank water posing these elevated cancer risks. Our estimates are based on detailed evaluations of the EPA-collected occurrence data and the National Academy of Sciences (NAS) total cancer risk estimates.[3] Table 2 notes the total potentially fatal cancer risk that would be associated with drinking two liters of water containing arsenic at a given level for a lifetime, based upon the NAS estimates. Chapter 2 includes a further discussion of these data on risks and health effects, and how these estimates were derived.

As is clear from Tables 1 and 2, tens of millions of Americans are consuming tap water every day at levels that may pose a serious potentially fatal cancer risk and other health risks. Appendix A lists each public water system in which arsenic was found in the 25 states reporting data. The national map is intended to show the general areas that are hardest hit by the highest levels of arsenic. However, to determine whether arsenic has been found in a particular public water system, according to EPA□s database, readers should refer to the table of water systems reported in Appendix A. The map cannot be used by itself to identify whether a particular water system has an arsenic problem, because often there are several water systems located immediately adjacent to each other, and the map was generated at a scale that cannot be used to identify precisely which water system contains a given level of arsenic.

Table 1: Arsenic Levels in Tap Water Systems in 25 States -- Low and Best Estimates

Average Arsenic Level (in ppb)	Low Estimate* of Number of Water Systems Affected	Low Estimate* of Total Population Served	Best Estimate** of Number of Water Systems Affected	Best Estimate** of Total Population Served
None detected	15,624	40,619,400	15,624	40,619,400
Detected, <1*	2,068	28,017,372	884	5,925,297
≥ 1 and <3	2,935	19,994,024	3,146	25,711,312
≥ 3 and <5	1,321	7,440,564	1,947	17,494,651
≥ 5 and <10	1,348	5,033,538	1,652	10,611,259
≥ 10 and <15	535	1,451,616	566	2,075,157

≥ 20 and <25	171	269,393	173	270,352
≥ 25 and <50	280	354,802	283	376,542
≥ 50	66	99,736	66	99,736
TOTAL	**24,599**	**103,523,971**	**24,599**	**103,523,970**
TOTAL at or above 1 ppb (0.5 ppb presents the highest cancer risk EPA traditionally allows in tap water)	6,907	34,887,199	8,091	56,979,263

*The low estimate is based on the assumption that any nondetect, no matter what the reporting limit, contained no arsenic, even if other samples showed arsenic was present. This highly conservative analysis results in a large number of systems having average concentrations below 1 ppb, because all reported nondetects, no matter what the reporting limit, are averaged as zero. See the discussion in the text for more details on how these averages were calculated.

** The best estimate is the estimated mid-average level of each system, which is the average of the detected levels of arsenic and, for those systems for which there was at least one detect of arsenic, one-half the level of detection for all nondetects. See the discussion in the text for more details on how these averages were calculated.

Table 2: Lifetime Risks of Dying of Cancer from Arsenic in Tap Water

*Based upon the National Academy of Sciences' 1999 Risk Estimates**

Arsenic Level in Tap Water (in parts per billion, or ppb)	Approximate Total Cancer Risk (assuming 2 liters consumed/day)
0.5 ppb	1 in 10,000 (highest cancer risk EPA usually allows in tap water)
1 ppb	1 in 5,000
3 ppb	1 in 1,667
4 ppb	1 in 1,250
5 ppb	1 in 1,000
10 ppb	1 in 500
20 ppb	1 in 250
25 ppb	1 in 200
50 ppb	1 in 100

*See note 3 and Chapter 3 for details on how we calculated total cancer risk based on an extrapolation of NAS's risk estimates, which assumed a linear dose-response and no threshold.

WATER SYSTEMS WITH ELEVATED LEVELS OF ARSENIC AND STATE MAPS SHOWING DISTRIBUTION OF ARSENIC PROBLEMS

Arsenic contamination of tap water is not a problem limited to a few pockets of the nation, nor is it limited in scope to small water systems. Tables 3 through 5 present summary data showing some water systems in which the EPA and state data indicate serious arsenic contamination problems may be found.

In addition, using ArcView Geographic Information System (GIS) software, and the latitude and longitude coordinates for public water systems reported in EPA's Safe Drinking Water Information System (SDWIS), NRDC has developed 25 state maps showing the regional variations in arsenic levels in tap water. The larger the dot, the larger the population served water system. In addition, we used graduated red coloration to show the concentration of arsenic found in the water, from light pink (representing low concentrations of arsenic) to bright red (representing mid-level arsenic levels) to dark red (representing severe arsenic contamination). In addition, NRDC wanted to give readers a picture of where arsenic was being searched for but *not* found. We used separate maps with graduated blue-green coloration to represent nondetects, with light blue-green representing nondetects using low levels of quantification (for example 1 ppb), and darker blue-green representing nondetects using high limits of quantification (for example 10 ppb).

As is clear from these tables and the 25 state maps, although arsenic contamination of tap

risk of fatal cancer).

Note: Only the national map is included in the online version of this report.

How Average Arsenic Levels are Calculated in This Report and in Appendix A

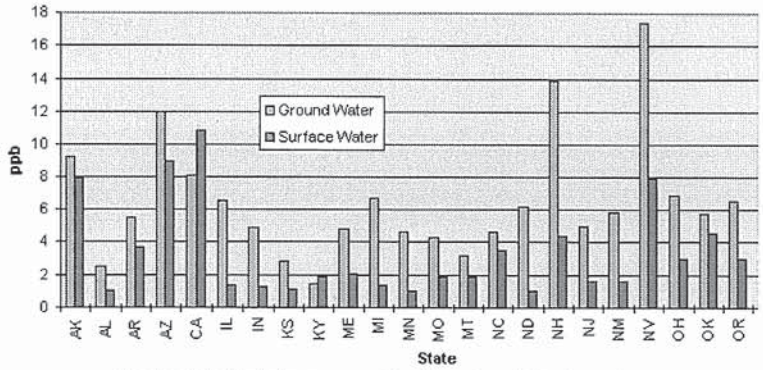
Arsenic levels can vary with time, and old samples often used cruder analytical techniques that could not detect low arsenic levels (below 10 parts per billion). We found that the so-called reporting limits for arsenic (that is, the lowest level of arsenic in the water that states require to be reported) in many states was 5 to 10 ppb in the 1980's and even in the early 1990's. Figure 3 shows that in some states, such as California, many water systems testing their water for arsenic were allowed to report as nondetected any level of arsenic below the state□s relatively high reporting limits.

In many cases, those reporting limits later were lowered, due to improved analytical methods, and arsenic started to be reported in the water of many more communities, as would be expected. This presented a problem for our analysis: when a water system had for years not reported arsenic, and then reported it when the reporting limit dropped, how should we calculate the arsenic level for that system? Additionally, a relatively small number of water systems had very inconsistent reported levels of arsenic over time, and we had to decide how to report their average levels as well. We decided that when a water system conducted multiple tests of its water, we would use two different averaging techniques to estimate the arsenic exposure for consumers of that water:

- **First, we calculated a very conservative low average**, which assumes that when arsenic was not reported as detected, there was absolutely no arsenic in the water at that time, even if the limit of detection was high (for example, 10 ppb), and even if other tests showed that arsenic was present in the water at levels somewhat below the previous reporting limit. For example, if a water system did five tests when the reporting limit was 10 ppb from 1985 to 1990 and found no arsenic, and then tested twice in 1993 to 1995 when the reporting limit was 3 ppb, and it found 8 ppb both of those later times, the low average calculated for that system would be 2.3 ppb (that is, [0 ppb + 0 ppb + 0 ppb + 0 ppb + 0 ppb + 8 ppb + 8ppb] □ 7 measurements = 2.3 ppb).

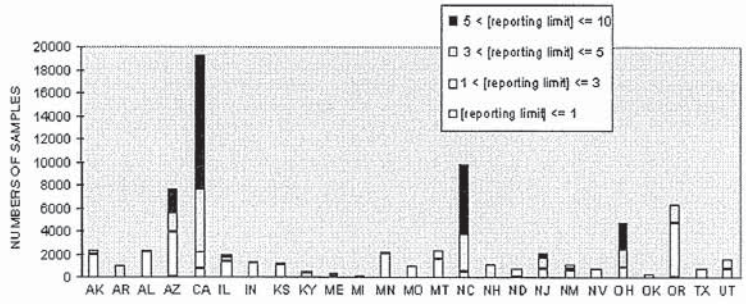
- **Second, we based our best estimate** on a calculated mid-average, which assumes that if at least some arsenic was detected in a water system at some time, then whenever arsenic was not reported as detected, it was present at a level of one half of the reporting limit. Using the same example, if a water system had five tests when the reporting limit was 10 ppb from 1985 to 1990 and found no arsenic, and then tested twice in 1993 to 1995 when the reporting limit was 3 ppb, and found 8 ppb both of those later times, the mid-average calculated for that system would be 5.8 ppb (that is, [5 ppb + 5 ppb + 5 ppb + 5 ppb + 5 ppb + 8 ppb + 8 ppb] □ 7 measurements = 5.8 ppb).

Figure 2: State Average Arsenic Concentrations for Systems Finding Arsenic



Based on best estimate of average arsenic levels for systems that found arsenic. Systems with all non-detects excluded.

Figure 3: Number of Tap Water Arsenic Samples, and the Lowest Level of Arsenic Required to Be Reported, by State (Reporting Limits)



Notes

3. As is discussed in Chapter 3, NAS estimated that, considering lung and bladder cancers death studies, the total cancer risk at the current tap water standard of 50 ppb "could easily" be 1 in 100. NAS, *Arsenic in Drinking Water*, at 8, 301 (1999). The NAS also noted that while there may be some indication that arsenic may not have a linear dose-response relationship at low doses, these data are "inconclusive and do not meet EPA□s 1996 stated criteria for departure from the default assumption of linearity." *Ibid* at 7. Thus, as discussed in Chapter 2, we assume, as did NAS, that dose-response is linear with no threshold, and that the total lifetime potentially fatal cancer risk of consuming two liters per day of arsenic-contaminated water poses the risks noted in Table 2. While NAS did not explicitly calculate risks posed by water with arsenic at levels below 50 ppb, its analysis was used to develop Table 2.

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Chapter 2
AN OVERVIEW OF THE SCIENTIFIC AND HEALTH ISSUES RAISED BY ARSENIC REGULATION

WHAT ARE THE KEY SCIENCE AND HEALTH ISSUES FOR ARSENIC REGULATION IN TAP WATER?

There are several important public health issues raised by the presence of arsenic in America□s tap water, including:

(These issues are discussed in this chapter.)

1. Why should the public care about arsenic in drinking water?
2. What are some of the environmental and biological characteristics of arsenic that are important to human health?
3. What are the adverse health effects of the various chemical forms of arsenic found in U.S drinking water?
4. Who in America is at special risk for adverse health effects from arsenic?

(These issues are discussed in the following chapter.)

5. What can we conclude about the adequacy of the U.S. EPA□s current drinking water standard for arsenic?
6. What can we conclude about the adequacy of other regulatory guidelines or standards for arsenic, for example the EPA reference dose (RfD) for ingested arsenic?
7. What can we conclude about what a health-protective level of arsenic in American drinking water supplies should be to prevent cancer and noncancer effects in American populations?
8. How can we prevent arsenic from getting into drinking water, or remove it from drinking water once it□s there?

ANALYSIS AND DISCUSSION

Why should the public care about arsenic in its drinking water?

Arsenic is an element of the earth's crust that has many economic and industrial uses. However, it also is highly toxic in many of its chemical forms, even at the low concentrations often found in drinking water. Arsenic itself, as the core element in various arsenic compounds, remains unaltered even though it may bind or unbind with other elements or undergo changes in valence, or charge state. This scientific reality has many implications for how the element moves through the human environment and how we can effectively regulate it.

Some drinking water arsenic comes from contamination by human activities. For example, arsenic can be released by industrial or mining waste sites, or can seep from a pesticide dump site into groundwater serving as a community water source. Other drinking water arsenic occurs naturally. Thus, water supplies from wells drilled into groundwater aquifers that can be laced with geochemical arsenic.

In fashioning *remedies* to the problem of arsenic contamination in drinking water, it may be important to consider the origin of the arsenic. But no matter the source of arsenic, public health concerns dictate that the problem be solved promptly. Where the arsenic contamination is from human activity, waste cleanups (such as Superfund cleanups) may solve the problem, while in other cases the only remedy available may be arsenic removal at the drinking water treatment plant. The bottom line is that as a matter of community and preventive medicine, we must seek to minimize or prevent adverse health effects and risks from arsenic in tap water.

What are some of the environmental and biological characteristics of arsenic that are important with respect to its effects on human health?

Tap water is one important way that people are exposed to arsenic, but they may also encounter arsenic in other environmental media, such as food, dust, soil, and ambient air. Toxic forms of arsenic are harmful to people no matter how they get into our bodies. Water can be the predominant source of the toxic forms of arsenic for many Americans, but in order for arsenic to be a health concern, it is not necessary that drinking water be the sole or dominant source of human arsenic intake. In other words, arsenic levels in our blood increase no matter what the source, so more arsenic in toxic forms from tap water or any other source increases our health risk.

This environmental and biological reality prevents our viewing tap water arsenic in isolation. If we chose to quantify health risks only for drinking water arsenic and did not consider suspected or known contributions from other human arsenic intake sources, we might well be underestimating overall or aggregate health risks. That is, our risk numbers would be at

contaminants and associated human exposures than others. This multimedia, integrated risk concept is particularly critical in the case of drinking water arsenic. Tap water arsenic is more easily controlled through centralized regulation, for example, controls on community water supplies, than arsenic in various dispersed sources and pathways, such as arsenic in soils, arsenic in home remedies popular in certain cultures, contaminated garden crops, or localized air arsenic emissions from smelters. Consequently, the regulatory attention given to arsenic in water is especially critical.

One characteristic of drinking water arsenic of special concern to regulators and scientists is the element□s typical occurrence in an especially toxic form, inorganic oxyarsenic. Oxyarsenic occurs in two different charge states (or valences) of importance here: pentavalent, which has five valence electrons (essentially points at which other chemical groups can attach to it), and trivalent, which has three such valence electrons, or attachment points. These forms are associated with a variety of cancer and noncancer toxic effects in humans. A wealth of recent health and scientific data identify trivalent and pentavalent oxyarsenic as equally toxic under the typical long-term, lower-level exposures to these arsenicals sustained by human populations. Earlier, crude studies in which test animals were fed large quantities of either valency form under acute, that is, very short-term, conditions seemed to show some difference in the way the animals□ metabolisms reacted, but we now know that result mainly related to the high-dose, short-time conditions of the studies. These conditions do not apply to long-term exposures of human populations to lower, but still toxic, exposure levels.

Most Americans are adept at recognizing visible or "macro-scale" acute and chronic (continuing) hazards to their health and readily accept the usual characterizations of those hazards by experts. Examples include acute injuries from fire and various chronic diseases linked to smoking. But many people are less aware of environmental contaminants and their toxic potentials. Many toxic contaminants such as arsenic occur in the environment at extremely low concentrations, yet these levels still can be high enough to be of health concern because they can be toxic at trace (part-per-million, ppm) or ultra-trace (part-per-billion, ppb and part-per-trillion, ppt) levels. In some cases, the injuries to human health from exposure to contaminants may only be seen after persistent contact with the contaminant for years or even decades; in other cases, complex medical and laboratory tests must be done to establish their presence.

What are the adverse health effects of arsenic in those chemical forms likely to occur in America□s drinking water?

The public□s perception of arsenic is still largely literary and forensic (stemming from such classics as the Joseph Kesselring play *Arsenic and Old Lace* and the film it inspired), and is most often recognized as the poison of choice for homicide, suicide, and other nefarious activities. This perception of arsenic toxicity represents only its most severe form. Such poisonings are acute, triggered by ingestion of very high amounts of inorganic arsenic (such as oxyarsenic) over a short time. When arsenic is ingested in large amounts deliberately or inadvertently, it produces a constellation of severe and often fatal injuries to the cardiovascular, gastrointestinal and nervous systems. This report examines the less-dramatic (but perhaps more important overall) dose-response and public health implications of widespread lower-level arsenic exposure of populations or their subsets.

We are concerned with arsenic exposures and toxic responses that are long term, occur at relatively much lower doses than those producing acute, fatal poisoning, and affect entire populations or population segments rather than a toxic outcome reported for a specific individual. In fact, we now know that the levels of arsenic and other elements in the environment that are toxic are so low that scientists could not previously have anticipated adverse effects without the growing scientific database of human epidemiological, experimental animal, and toxicological mechanistic studies. This large and evolving database defines significant toxic risks across a wide spectrum of doses or exposures.

The available information on the adverse health effects of arsenic in drinking water and in other media are to be found in various authoritative expert consensus documents listed in this paper□s illustrative bibliography. These include documents of federal agencies such as the EPA, and independent scientific bodies such as the National Academy of Sciences (NAS). These treatises and individual critical reviews and research papers form the foundation of the analyses and conclusions presented in this paper. This analysis and its conclusions about the impact of tap water arsenic on public health are focused on adverse effects associated with the element□s toxicological character. Some experimental animal studies of arsenic□s biological activity in recent years have suggested a potential role for the element as a nutrient in those animal species tested. Nutrient roles at very low intakes and toxic effects at higher intakes are not uncommon with environmental elements and do not, in any way, ease the need for control of excessive exposures. A nutrient role in humans, within the framework of the battery of widely accepted criteria to establish such roles, has not been determined for arsenic.

Indeed, the NAS□s recent report on arsenic in drinking water notes that "studies to date do not provide evidence that arsenic is an essential element in humans or that it is required for any essential biochemical process." (NAS, 1999, p. 259) Any nutrient role would have to be at very low levels, in common with other elements with dual bioactivity. It is highly unlikely that arsenic could ever be regulated to levels so low that any yet-to-be-established human deficiency for the element would occur. This topic was discussed in detail by the author elsewhere (Mushak, 1994).

Arsenic-Induced Skin and Internal Cancers

Long-term exposure of nonoccupational human populations to environmental arsenic is associated with skin cancer and with various internal cancers, such as bladder, kidney, liver, and lung cancer. The NAS□s 1999 report on arsenic in drinking water concluded that arsenic is "known" to cause skin, bladder and lung cancer, and noted that there is substantial evidence that arsenic in drinking water is associated with other cancers, including cancers of the liver and kidney.

Workers encountering airborne arsenic in the workplace are known to be at high risk for lung cancer and possibly other cancers as well. Nonworker populations who have been

drinking water. Consult the bibliography for further details. Among the key references are the 1984 EPA health assessment document for arsenic, the 1988 EPA assessment of some specific issues for arsenic and human health, the EPA 1996 document for arsenic health assessment, and the 1999 NAS detailed report on cancer and other adverse effects, *Arsenic in Drinking Water*.

Some of the most compelling evidence for arsenic as a carcinogenic (cancer-causing) substance is to be found in various studies of a large Taiwanese population exposed to arsenic in their drinking water. Also compelling are data showing elevated cancer rates in people who drank arsenic-contaminated water in Argentina and Chile. The Taiwanese study population was huge, numbering more than 40,000 subjects, and included a large control population with more than 7,000 individuals. Study groups of these sizes in the environmental epidemiology of toxic elements are not very common. The earliest cancers appearing in these Taiwanese and in other groups were skin cancers -- consisting of various histopathological types -- followed later in their lives by cancers of internal organs -- bladder, kidney, liver, lung. Arsenic-associated skin cancers occur in specific body areas not exposed to sunlight: the trunk, soles, and palms. Therefore, arsenic cancer lesions can be distinguished from cancers caused by sun exposure.

Additional strong evidence that arsenic in drinking water causes cancer is from Chile, where a larger population was studied than that in Taiwan -- more than 400,000 people. Researchers evaluating this Chilean population found marked increases in mortality for bladder and lung cancer in particular. Approximately 7 percent of all deaths over age 30 could be attributed to arsenic (Smith AH et al. 1998).

Some regulators and others have argued that the threat to life caused by arsenic-associated cancers differs between skin cancers and cancers of the bladder, kidney, liver, or lung. They argue that the latter cancers collectively offer a higher mortality risk and are therefore more life-threatening. This distinction is hardly reassuring, nor does it counsel neglect of skin cancer as a public health concern. Only some of the arsenic-associated cancers arising in skin and associated with arsenic are benign (the basal cell lesions) while the squamous cell carcinomas may metastasize to other organs. In any event, the findings of internal organ cancers in reports that are more recent than those for skin cancers have significantly reinforced public health and safety concerns associated with arsenic.

While some regulators have suggested that skin cancer should be downgraded as a health concern because it sometimes is not fatal, is inappropriate to consider only fatal cancers in assessing arsenic□s risks to public health. Nonfatal cancers inflict enormous emotional and economic costs to the victims of these cancers, their families, and society as a whole.

Not surprisingly, new findings on arsenic carcinogenesis have generated a number of recent studies, such as ones looking at how representative the Taiwanese population data are for risk analyses in U.S. communities exposed to arsenic in drinking water and other environmental media. Some in industry and their representatives have challenged the Taiwanese data, despite the fact that the Taiwanese data are the most extensive to date, and that rates of cancers associated with drinking water arsenic are proportional, considering varying exposure levels, to those found in other geographically distinct areas, such as Argentina and Chile.

To date, however, no one has successfully challenged the view by U.S. regulators and the NAS that the Taiwanese and Chilean studies provide strong evidence of arsenic□s carcinogenicity in humans. Several appraisals of these challenges merit comment and the author noted these in a 1995 paper (Mushak and Crocetti, 1995).

Some attacks on the Taiwanese data have argued that the nutritional status and metabolic aspects of the study population put it at greater risk for toxicity from arsenic exposures than U.S. communities. However, the results of these studies have not produced any convincing challenges to the scientific validity of the data on nutritional grounds (Mushak and Crocetti, 1995). Impaired nutrition as a factor producing increased arsenic toxicity in Taiwanese, even if it were valid, is hardly an exclusionary criterion for comparisons with Americans. The argument of differential nutrition requires that we assume Americans exposed to drinking water arsenic, unlike the Taiwanese, are all well-nourished and at lower risk for arsenic toxicity. This is simply untrue. Undernutrition is a chronic public health and societal problem in America, including for those in the high-risk arsenic groups, the elderly and young children (see below).

Industry and some others have cited additional factors to argue that one cannot compare the Taiwanese exposures to arsenic to American arsenic exposures. They have claimed that other contaminants, such as alkaloids, in the Taiwanese well water are the culprits or at least co-culprits. Again, this argument is unconvincing. For example, arsenic produces cancers and other arsenic-associated effects in a number of other exposure settings comparable to the Taiwanese situation, but where alkaloidal contaminants are absent.

Others have held that the Taiwanese have genetic determinants that alter arsenic metabolism in the body, resulting in a different likelihood of cancers, but genetic predisposition to arsenic-associated cancers also remains an open issue. Some recent studies suggest that there may be genetic polymorphism (that is, many different human genetic types) in the enzyme pathway which is thought to detoxify arsenic in our body ("detoxifying biomethylation"), but such polymorphism has yet to be linked to risk differences for various cancers. Furthermore, we do not know the range of genetic diversity in Americans with respect to these arsenic methylation enzymes. Nor do we have a good handle on the mechanisms of arsenic carcinogenesis, or the metabolic transformations of the element. Research has also suggested that increased arsenic methylation may be linked to a higher cancer risk. This author first hypothesized in 1983 that the body's metabolic diversion of methyl groups away from needed bodily processes to detoxifying arsenic could be a factor in causing arsenic toxicity (Mushak, 1983). Thus, as NAS's 1999 report concluded, there is no basis on which to rest any argument that the solid body of Taiwanese data associating arsenic in tap water with several cancers, or the confirmatory data from Argentina and Chile, should be rejected.

These studies, taken together, paint a compelling picture. They have lead the NAS and many other august bodies to conclude that arsenic in drinking water is known to cause cancer in humans.

including hyperkeratosis, a pronounced scaly skin condition, and changes in pigmentation. These skin changes are so characteristic that the medical literature notes that laypeople could easily identify workers who used arsenic as a sheep-dip pesticide, simply because of their obvious skin lesions.

Ingested inorganic arsenic produces both central and peripheral nervous system effects in exposed humans. Peripheral nervous system effects on both sensory and motor nerve function mainly harm adults, while very young children are more susceptible to central nervous system effects on the brain. The effects of arsenic exposure in children may persist over the long term, based on data described in EPA□s 1984 health assessment document (EPA, 1984). Irreversible toxicity must obviously be viewed much more seriously than reversible effects. Once injury has occurred, simply reducing the exposure does not undo the harm.

Exposures to arsenic in drinking water and other media also cause toxic effects on peripheral blood vessels. In its extreme form, vessel toxicity takes the form of a dry gangrene, called Blackfoot Disease, particularly noted in the more heavily exposed Taiwanese. Lower exposures were linked to a very painful peripheral blood vessel disorder in Chilean children exposed to drinking water arsenic, resembling Raynaud□s Disease. The latter arises from arterial and arteriolar spasm and contractions leading to impaired blood flow and cyanosis (inadequate oxygen reaching the tissues). Studies also have linked arsenic exposure from drinking water to higher rates of diabetes.

Data from the Taiwanese studies and from studies of other populations reveal that there is a dose-response relationship for ingested water arsenic and several non-cancer toxic effects (NAS, 1999; EPA, 1984, 1996). By dose-response relationship, we simply mean that as the arsenic intake increases, both the frequency and the severity of toxic effects increase in the exposed people. This type of dose-response relationship is one of the most important pieces of evidence that health scientists use to determine that a toxic chemical actually causes a particular toxic effect. For example, scientists have documented a dose-response relationship in human populations showing that increased exposure to arsenic in drinking water causes more frequent and more severe skin lesions and serious vascular effects.

Arsenic also has been linked to injury to the cardiovascular system, a particular concern in the United States where cardiovascular diseases already are a major public health concern. Elevated arsenic exposures should be considered a potential added risk factor in addition to other widely-recognized risk factors for cardiovascular diseases.

Who in America is at special risk for adverse health effects from environmental arsenic?

Different people respond to exposure to arsenic or other toxins in different ways. The toxic responses can vary greatly, even when people are exposed to the same amount of a contaminant such as arsenic.

There are many reasons for this variability in toxic response, arising from either intrinsic factors or extrinsic causes. Intrinsic factors are those peculiar to the individual, and over which the individual has little control, for example, gender, age, race, stage of development, or group behavioral traits. Extrinsic factors are those outside the individual□s characteristics and include length of exposure to a toxic substance. A general discussion of characteristics that can heavily influence the differential toxicity of toxins to different individuals, in the context of lead, is included in the NAS□s 1993 report on populations sensitive to lead exposure (NAS, 1993a), of which the chief author of this report was a co-author. A second NAS report appearing in 1993 (NAS, 1993b) detailed the increased sensitivity of very young children to pesticides compared to adults. As discussed below, many of the basic principles that may lead to higher risks in children from lead or pesticides (for example, children□s immature detoxification systems and higher exposure to drinking water per unit of body weight) apply to arsenic.

Variability in the human population□s sensitivity to environmental contaminant toxicities is now an accepted principle in scientific, regulatory, and legislative quarters. This acceptance by science is found in numerous documents and individual research papers dealing with environmental contaminants, illustrated in the cited treatises and papers. Agencies such as the EPA regulate environmental metals and other contaminants with an eye to those populations at special risk, not "average" populations. That is, population segments with particular biological sensitivities or enhanced exposures are identified in relevant rulemaking for adequate protection from exposure and associated toxic harm.

In 1996 Congress enacted the Food Quality Protection Act (FQPA), Pub. L. No. 104-170, 110 Stat. 1489 (1996), partly in response to the 1993 NAS report on children and pesticides (NAS, 1993b), *Pesticides in the Diets of Infants and Children*. The FQPA mandates special protection for young children from pesticides, including a general requirement that an added tenfold margin be included to ensure safety for children, unless reliable data show that such an additional safety factor is unnecessary to protect children. Similarly, Congress adopted the "Boxer Amendment" in the 1996 Safe Drinking Water Act Amendments, which requires EPA to consider children, infants, pregnant women, and other especially vulnerable subpopulations in setting drinking water standards. SDWA □□ 1412(b)(1)(C), (b)(3)(C)(5), 1457(a).

We can readily identify two segments of the U.S. population that are at risk. First, older adults who have sustained elevated arsenic exposures over the long term are at special risk. Both cancer and noncancer toxic effects can occur in these individuals as a result of their prolonged exposure.

Second, very young children can be at elevated risk. The very young, especially infants and toddlers, are more likely to come into direct contact with arsenic. For instance, they often put arsenic-contaminated items in their mouths. In addition, pound for pound they consume more arsenic and other contaminants than adults. A higher arsenic intake rate for children per unit of body weight has been shown, as seen for example in the 1999 study of Calderon et al. evaluating American subjects. Additionally, the very young, being less able to defend against toxicants than are older children or adults. In the case of arsenic, we have to take into account that the very young do not detoxify arsenic as efficiently as adults, as shown in recent studies. Data from a study by Concha (1998a) indicate the fraction of toxic inorganic

percent inorganic form, suggesting that children may be less able to detoxify arsenic and therefore may be more susceptible to its toxic effects. Data from a study by Kurttio et al., (1998) indicate that this differential in biomethylation-detoxification may persist over many years. We also must consider that children are more sensitive to the central nervous system effects of arsenic than adults are, and that children who sustain central nervous system injuries from arsenic may have irreversible injury, as noted above (EPA, 1984).

A third high-risk population, not fully characterized, is fetuses, which can be exposed to arsenic by way of maternal exposure. Arsenic, like a number of other environmental contaminants, crosses the placental barrier in pregnant mammals (for example, NAS, 1999). The fetus is even more biologically sensitive than the infant and toddler. Arsenic intoxication of the conceptus (human embryo relatively shortly after conception) can potentially target both organogenesis (the generation of the developing vital organs) in the embryo stage and further development in the later, fetal stage. While no in-utero arsenic effects have been documented for human exposures, we do know that oral intake of arsenic in experimental animal studies produced birth defects, impaired fetal growth, and reduced the survival of fetal and newborn animals (see, for example, NAS 1999). Of particular concern here is the recent finding that arsenic enters the fetal circulation in pregnant women by at least the third trimester, and that the level of arsenic in umbilical cord blood approaches the maternal arsenic level (Concha et al., 1998b).

Because of variations in human sensitivity to arsenic, including indications that children may be more vulnerable to this toxin, the NAS (1999) suggested that "a wider margin of safety might be needed when conducting risk assessments of arsenic because of variations in metabolism and sensitivity among individuals or groups"(p. 5). The next chapter, dealing with conclusions about the regulatory status of drinking water arsenic in America, focuses on these risk groups.

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Arsenic and Old Laws
A Scientific and Public Health Analysis of Arsenic Occurrence in Drinking Water, Its Health Effects, and EPA's Outdated Arsenic Tap Water Standard

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Chapter 3
CONCLUSIONS FOR SAFE REGULATION OF DRINKING WATER

What can we conclude about the adequacy of the U.S. EPA□s current drinking water standard for arsenic?

The present EPA drinking water standard, as an enforceable Maximum Contaminant Level (MCL), is 50 micrograms of arsenic per liter water (50 µg/L, equivalent to 50 parts per billion, or ppb). This value has not changed since 1942, and was promulgated with few scientific underpinnings. There is therefore little scientific support for its regulatory adequacy. This MCL was issued before the accumulation of the large body of scientific and human health data produced over the last 30 to 40 years, a period that included the Taiwanese studies and numerous authoritative treatises on arsenic, including some from the NAS and EPA. As long ago as 1962, the U.S. Public Health Service recommended that water containing more than 10 µg/L (or ppb) of arsenic (one-fifth of the still-current standard) should not be used for domestic supplies.

Congress has directed EPA to update the 1942 arsenic standard three times -- in 1974, 1986, and 1996. A court ordered EPA to complete this task in the early 1990□s, but several extensions were granted. EPA still has not updated the standard. In a legislative mandate in the Safe Drinking Water Act Amendments of 1996, Congress again directed EPA to publicly *propose* an updated arsenic standard based on current evidence by January 1, 2000, a deadline that EPA has now, again, missed. EPA is then required to promulgate the *final* arsenic standard by January 1, 2001.

The current scientific and health risk assessment status of arsenic within that mandate makes it clear that EPA□s current MCL of 50 µg/L is grossly inadequate for protecting public health. The extent of that inadequacy is effectively captured in the NAS report, *Arsenic in Drinking Water* (NAS, 1999). The report focused heavily on risk assessment estimates for human cancer frequencies as a function of drinking water and food arsenic and derived cancer risks for arsenic in environmental media, particularly drinking water. Our analysis concurs strongly with the academy□s findings and recommendations as well as the following conclusion:

> On the basis of its review of epidemiological findings, experimental data on the mode of action of arsenic, and available information on the variations in human susceptibility, it is the subcommittee□s consensus that the current EPA MCL for arsenic in drinking water of 50 µg/L does not achieve EPA□s goal for public-health protection and, therefore, requires downward revision as promptly as possible (NAS, 1999, pp. 8-9).

The NAS report did not recommend a specific MCL below 50 that would be fully health protective. It did, however, provide a series of cancer risk assessments for cancers of the skin and internal organs. This approach for bladder and lung cancers employed the traditional straight-line extrapolation from rates at elevated arsenic exposures. Put differently, the NAS assumed -- as is usually assumed by scientists based on traditional principles of toxicology, unless there is strong evidence to the contrary -- that there is a direct, linear relationship between cancer risk and arsenic exposure. The academy committee members, correctly and conservatively (with respect to the best health protection), noted that low-dose extrapolation models based on available data may *or may not* be "sublinear" compared to linear extrapolation. That is, arsenic at extremely low doses may, or may not, cause relatively less cancer risk per microgram than it does at high doses. However, the NAS experts concluded, the evidence for such "non-linear" models of arsenic-associated cancer risk is not compelling enough to rule out the traditional linear approach, so the health-protective linear approach should be used. The NAS scientists then used studies of people who had been exposed to arsenic in their tap water at elevated levels (for example in Taiwan) to model, or estimate, the risks of people exposed to lower levels.

The 1999 NAS report calculated that arsenic consumption in drinking water at the current EPA MCL would produce a male *fatal bladder* cancer lifetime risk of 1 per 1,000 to 1.5 per 1,000, using a linear extrapolation approach. Factoring in lung cancer risk and its relative robustness compared to bladder cancer (lung cancer risk is about 2.5 times greater than bladder cancer risk), an overall internal cancer risk rate "could easily result in a combined lung cancer risk" of 1 percent, or 1 in 100, according to the NAS□s 1999 report (p. 8). The high level of cancer risk from arsenic ingestion in water at the present MCL does not account for concurrent intakes of carcinogenic arsenic from food or idiosyncratic sources (for example, certain prepared ethnic remedies that contain arsenic). In the past, EPA estimated a lower cancer risk from arsenic in tap water than did NAS in 1999. For example, EPA□s Integrated Risk Information System (EPA, 1998) estimated about a 10-fold lower cancer risk for arsenic than the more recent NAS study (NAS, 1999), apparently in part because EPA evaluated only bladder cancer risks, whereas NAS considered the higher risk of lung cancer as well, based on recent studies. We believe the NAS risk estimates are

generally supported by studies of people drinking relatively low levels of arsenic in their tap water. For example, a recent study from Finland (Kurttio et al., 1999), found that Finns who drank water containing low levels of arsenic (less than 0.1 ppb) had about a 50 percent lower risk of getting bladder cancer than their countrymen who drank water containing somewhat more arsenic (0.1 ppb to 0.5 ppb). Significantly, people who drank more than 0.5 ppb arsenic had more than a 140% increase in bladder cancer rates compared to those who consumed levels less than 0.1 ppb.

The pros and cons of models that characterize cancer risk bring up the role and judgment of risk assessors. The NAS's 1983 seminal document on risk assessment in regulatory agencies and elsewhere in the federal government (NAS, 1983) suggested a four-part paradigm for quantifying health risk that is now widely used in various incarnations by governmental agencies and others. The 1983 report also repeatedly made note of the role of judgment in the risk assessment process, a fact too often ignored by interested parties viewing regulatory risk assessment models. Without a totally clear scientific consensus on the guaranteed best scientific approach, or in the face of equally acceptable approaches, we must opt for the scientific approach that provides the maximum protection for human populations. The linear extrapolation approach adopted by the NAS subcommittee is in full accord with this principle, which should apply to assessment of cancer risks for environmental contaminants.

What can we conclude about the adequacy of other regulatory guidelines or standards for arsenic, for example the EPA reference dose (RfD) for ingested arsenic?

EPA issues guidelines for the intake levels of environmental contaminants that the agency generally considers to be free of toxic risk during long-term, that is, lifetime, exposures. In the case of oral intakes these values are called reference doses, RfDs. They are expressed in milligrams (mg) of contaminant daily intake per unit body weight in kilograms (kg-day). RfDs, being derived for oral intakes, do not usually take account of other routes of intake. Inhalation of contaminants might be a significant exposure route, in which case a reference concentration, RfC, expressed as milligrams per cubic meter of ambient air, may also be used. It is important to note that if more than one exposure route is significant, we must recognize that the RfD is less protective than we would otherwise conclude if we thought that arsenic in drinking water was the sole route of exposure. EPA, in its general description of the RfD approach, notes the need to take account of other intake routes (EPA, 1993).

EPA has set the RfD for ingested inorganic arsenic, the amount viewed as not being linked to any health risk, at 0.0003 mg/kg-day (0.3 µg/kg-day). This value is derived for skin hyperpigmentation and keratosis and potential vascular effects. Analyses in the preparation of this paper, including a review of health effects data for the United States, found no currently valid and convincing reasons to say this value is too low. Thus, no higher RfD is warranted.

EPA's failure to fully consider risks to children in the RfD derivation is of concern. It is true that early childhood is only a fraction of the total lifetime interval considered when deriving an RfD for lifetime effects of arsenic. However, the relatively inefficient detoxification of a potent carcinogen and toxin by children, and the increased sensitivity (and higher exposure per unit of body mass) of children to arsenic-associated central nervous system effects, are serious issues. EPA should revise the current RfD downwards to account for the apparent elevated vulnerability of children; the data certainly do not support any upward revision of the current value.

In addition, EPA has not reconciled the health risks represented by the current RfD value based on noncancer toxic effects with the internal cancer risk estimates calculated for drinking water arsenic in the 1999 NAS report. The current RfD permits a "safe" daily intake by a 70 kg adult male of 21 µg arsenic per day. Risk-characterization estimates in the NAS report for the MCL value permit calculation of a cancer risk for this "safe" 21 µg daily intake that markedly exceeds any acceptable regulatory risk management guideline for cancer. Put differently, the amounts of arsenic intake that may be safe for noncancer risks are unsafe for cancer risks.

To protect children and infants, an RfD at least three-fold lower, 0.1 µg/kg-day, is certainly more defensible and more protective of identifiable at-risk populations in the United States. This adjustment is based upon standard EPA use of "uncertainty" factors for the RfD. The current uncertainty factor of three should be increased 10, the next generally permitted level for such a factor, based on concerns about the special susceptibility of children. Even such a lower RfD, it should be noted, would still present a cancer risk higher than EPA would generally consider acceptable. We recommend that the RfD be reduced to at most this level.

What can we conclude about what a health-protective level of arsenic in U.S. drinking water supplies should be to prevent cancer and noncancer effects in the U.S. population?

According to the data, we need a much lower and more protective EPA standard for drinking water arsenic and a much lower and more protective reference dose guidance level for arsenic.

Given the risk estimates for all internal cancers provided in the NAS's 1999 report, the current EPA MCL for arsenic must be revised downward to no higher than a value at the Practical Quantitation Level (PQL) of 3 ppb. EPA completed a thorough review of laboratory capabilities in 1999, and concluded that the PQL is 3 ppb (Miller, 1999). Thus, a new MCL of 3 ppb is reasonable, based on the newest analytical methodology assessment from EPA (which is more current than the 4 ppb figure cited by NAS, 1999, a level based on earlier studies, see, Eaton et al., 1994; Mushak and Crocetti, 1995).

- Our conclusion that the MCL should be 3 ppb is driven by practicality, that is, one cannot regulate below what one can measure for compliance. This does not say that values lower than the PQL of about 3 ppb pose no cancer risk; it only recognizes that quantification of these lower levels in drinking water is problematic at this time. While many laboratories can reliably detect arsenic at levels below one ppb, reviews of a

immediately seek to reduce the PQL for arsenic by developing and standardizing improved analytical techniques for arsenic. The only alternative to setting an MCL at the PQL would be for EPA to establish a "treatment technique" for arsenic, an approach that seems difficult to justify here since arsenic is reliably detectable down to the low ppb range.

- There is no scientifically sound reason for increasing the noncancer RfD value from 0.3 µg/kg-day to a higher value. To the contrary, as noted above, there is good reason to adjust the value lower. Adults ingesting the "safe" arsenic dose for noncancer effects will simultaneously be at too high a risk for internal organ cancers. While EPA□s risk management guideline for permissible skin cancer risk was changed to 1 in 10,000 in 1988, the guideline for the more dangerous, more often fatal internal cancers should remain at 1 in 1,000,000. One cannot get to anything near this cancer rate guideline with the present RfD value if one assumes significant contribution of carcinogenic inorganic arsenic from food.

- For these reasons, an RfD at least three-fold lower, 0.1 µg/kg-day, is certainly more defensible and more protective of identifiable at-risk populations in the United States.

How can we prevent arsenic from getting into drinking water, or remove it from drinking water once it□s there?

1. Preventing Arsenic From Getting Into Water Supplies.
Arsenic gets into drinking water from a variety of sources. Sources from human activities include:

- **Leaking of arsenic from old industrial waste dumps.** Arsenic is one of the most common contaminants found at Superfund sites, for example.

- **Leaching of arsenic from mines and mine tailings.** Some hard-rock and other mines expose arsenic-bearing rock to the elements, "liberating" the arsenic into the environment, and in some cases causing serious arsenic contamination of ground and surface water.

- **Runoff or leaching of old arsenic-containing pesticides from sites where they were heavily used.** In some cases, the old arsenic-based pesticides remain in the areas where they were applied, manufactured, or disposed of years ago, and can get into water supplies.

- **Heavy groundwater pumping.** Recent studies in Wisconsin and elsewhere have shown that heavy pumping of groundwater has increased arsenic levels in some wells. In some cases heavy pumping appears to have pulled water out of heavily arsenic-contaminated layers of rock that were not the primary aquifer being tapped but had not been sealed off from the well. In other cases, possibly because overpumping appears to have caused groundwater levels to drop, increasing arsenic-bearing rock contact with air and thereby increasing arsenic leaching).

Cleaning up old dumpsites under Superfund and related programs may reduce arsenic contamination in some systems affected by arsenic from industrial sites. Additionally, arsenical pesticide hot spots, and certain mine waste sites, are sometimes covered by Superfund or other cleanup laws and should be addressed in order to reduce water contamination.
Efforts to reduce leaching and drainage from mines and mine tailings by improving reclamation and mining practices should also be undertaken to reduce arsenic loading into many water sources. Furthermore, it is worth investigating whether reworking contaminated wells (for example, using a casing and cement to seal off arsenic-bearing rock layers that may be leaking water into the well) and/or reducing pumping rates may in some cases reduce arsenic levels in systems. Government officials and water systems should work with citizens to remedy these problems so water supplies are not contaminated by arsenic and do not need to be treated for arsenic removal.

2. Readily Available Treatment Technologies Can Remove Arsenic from Drinking Water.
The best way to avoid arsenic contamination from reaching our taps is to prevent it from getting into the environment in the first place. Where prevention is not possible, as when the arsenic occurs naturally, and when no alternative water source is available and the system cannot consolidate with another, cleaner water system, water treatment is readily available. Treatment already in use by some progressive water utilities has been demonstrated to reduce or essentially eliminate arsenic contamination of tap water. Among the effective arsenic treatment options EPA has identified (EPA, 1999; EPA 1994) are:

- **Modifying Existing Coagulation and Filtration.** Large water systems that already have coagulation and filtration technology (as most surface water systems do) can take simple steps to modify these processes to substantially reduce arsenic levels. Changing their use of iron or manganese oxidation, use of ferric chloride or ferric sulfate, and alum coagulation and filtration can reduce arsenic by 80 to 95 percent. These steps are relatively inexpensive.

- **Water Softening with Lime.** Many water systems already use lime to "soften" their water (that is, to reduce water "hardness" by removing the minerals calcium and magnesium). We now know that softening, if optimized, can reduce arsenic levels by 60 to 90 percent. It is about as inexpensive as coagulation and filtration modifications

waters, if the source water has high levels of selenium, fluoride, or sulfate, it is not as effective at arsenic removal.

- **Ion Exchange.** This technology, already used by many water systems, can remove arsenic effectively in most water. Again, however, if levels of certain other chemicals (such as sulfate, selenium, fluoride, or other dissolved solids) are too high, pretreatment using other technologies is needed to assure that adequate levels of arsenic are removed.

- **Electrodialysis Reversal.** Essentially the same process as used to clean blood at dialysis centers, electrodialysis takes advantage of the charge of particles (like arsenic) and a special membrane under the influence of an electric current, and can remove about 80 percent of arsenic from water.

- **Reverse Osmosis and Nanofiltration Membranes.** RO and NF membranes can remove 90 percent to more than 95 percent of arsenic. These membranes can reject substantial amounts of water, and therefore waste-stream recovery or other actions may be necessary in the arid West. Also, particularly if arsenic levels in the raw water are high, treatment or disposal of the concentrated brine created by removing the arsenic from the water can increase costs.

- **Point of Use and Point of Entry Treatment.** Under the 1996 Safe Drinking Water Act Amendments, water suppliers are authorized, under strict conditions, to use point-of-use filters (for example, RO units installed under kitchen sinks) or point of entry filters (for example, treatment devices in the basement at the point water goes into the home) to comply with drinking water standards. EPA studies have shown that these devices can be affordable and effective to treat for arsenic, and may be cheaper for small systems than installing centralized treatment. For this to work in a national rule, EPA would have to clarify utilities□ utility responsibility in assuring the continued operation and maintenance of such devices.

3. Treatment Costs to Remove Arsenic are Modest for Most Consumers.
For several years, EPA has been evaluating the cost of installing treatment to meet various Maximum Contaminant Levels (MCL) for arsenic. EPA's most recent public analysis (Taft, 1998) found that if the standard were lowered from the current 50 ppb down to 5 ppb, it would cost most households (those served by city systems serving 100,000 people or more) about $2 a month, and would cost up to $14 a month for people living in smaller towns (with 10,000 to 100,000 people). Even a standard as low as 2 ppb would cost city dwellers with arsenic problems about $5 a month, and those living in affected towns as small as 10,000 people would pay about $14 a month.
Systems serving over 10,000 people serve the vast majority of people affected by arsenic contamination. Our analysis of EPA□s 25-state arsenic database shows that about 9 out of 10 people (87 percent) who consume arsenic at a significant level in their tap water (over 1 ppb) are served by these systems serving more than 10,000 customers.
For the 13 percent of consumers who get their water from smaller systems, however, treatment costs can be significantly higher than they are for consumers in cities, because of the lack of economies of scale. Thus, EPA estimates that people drinking water from a system serving 3,300 to 10,000 people may have to pay as much as $20 a month, and the smallest systems (assuming the worst case and that no point-of-use or other devices were allowed) could reach $100 a month (Taft, 1998).
Using these figures, EPA has estimated that a 5 ppb arsenic rule would cost about $686 million per year, and a 2 ppb standard would cost $2.1 billion. However, EPA recently admitted (Taft 1998) that both these national cost estimates and the individual household cost estimates are probably overstatements of the true costs of treatment for several reasons:

- Most important, EPA assumed that all systems that exceeded the MCL would install full treatment of all of their water to get it well below the MCL. More recent analysis shows, however, that most water systems would actually treat only some of their water and then would blend it with untreated water, in order to produce water just under the MCL, to keep the costs down.

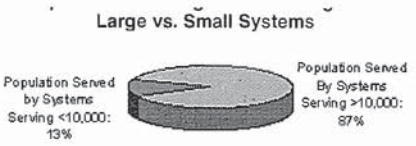
- EPA assumed that if a water system with multiple wells has just one or a few wells exceeding the arsenic MCL, the system will treat all of its wells, including those below the MCL; EPA now understands that this is extremely unlikely.

- EPA's estimates did not account for recent advances in treatment technologies, such as the newly understood ability of the relatively inexpensive ion-exchange treatment to effectively treat all but the highest sulfate waters.

- EPA□s estimates failed to account for improvements in water quality that are expected to be required by other EPA rules, such as the groundwater rule, the Stage 2 Microbial and Disinfection Byproducts rule, and the uranium rule, all of which are expected to drive many water systems to use treatment that will also reduce arsenic.

- The older EPA estimates do not consider the availability of point-of-use and point-of-entry devices now authorized by the 1996 SDWA Amendments, technologies that are substantially less expensive than centralized treatment for many small systems.

- EPA's cost estimates do not account for expected reductions in treatment costs as



* Significant is defined as presenting >1 in 10,000 fatal cancer risk, i.e. over 1 pp

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4. The States and Federal Government Should Assist Small Systems That Cannot Afford Arsenic Treatment.

Even with these reasons to believe EPA is overestimating costs, it is clear that at least some small systems will have to pay relatively high costs per household to have arsenic-safe water. For these smaller systems, federal and state assistance to improve treatment is available, and arsenic contamination should be a high priority for these drinking water funds. Additional federal and state funding through State Revolving Funds (SRF), USDA's Rural Utility Service, and other programs may also be needed. The SRF established by the Safe Drinking Water Act Amendments of 1996, which has not been fully funded since the act's passage, should be funded at least to the full authorized amount ($1 billion per year) to help smaller systems with arsenic problems.

Therefore, even using EPA□s high cost estimates,[4] a strict arsenic standard for tap water would be both sound public health policy and affordable for consumers. It is EPA□s obligation to protect the American public from arsenic contaminated tap water, by issuing a strict MCL of 3 ppb arsenic.

CONCLUSIONS

Americans should be able to turn on their taps and be sure that their drinking water is safe. Arsenic is perhaps the worst example of EPA□s failure to address a serious health risk from a chemical contaminant in drinking water. The agency has had over a quarter century, since the Safe Drinking Water Act passed in 1974, to adopt a modern tap water standard for arsenic, but has failed to do so. The time has come for the agency to act. Specifically, we recommend that:

- **EPA Must Immediately Propose and Finalize by January 1, 2001 a Health-Protective Standard for Arsenic in Tap Water.** The National Academy of Sciences (NAS) has made it clear, and we agree, that EPA should expeditiously issue a stricter Maximum Contaminant Level standard for arsenic. Based on available scientific literature and NAS risk estimates, this standard should be set no higher than 3 ppb -- the lowest level reliably quantifiable, according to EPA. Even an arsenic standard of 3 ppb could pose a fatal cancer risk several times higher than EPA has traditionally accepted in drinking water.

- **EPA Must Revise Downward its Reference Dose for Arsenic.** EPA's current reference dose likely does not protect such vulnerable populations as infants and children. Furthermore, "safe" arsenic intakes in the RfD present unacceptably high cancer risks. To protect children, EPA should reduce this reference dose from 0.3 micrograms per kilogram per day (µg-kg/day) to at most 0.1 µg-kg/day. For concordance with cancer risk numbers, EPA should reevaluate the RfD in more depth as expeditiously as feasible.

- **EPA Should Assure that Improved Analytical Methods Are Widely Available to Lower Detection Limits for Arsenic.** EPA must act to reduce the level at which arsenic can be reliably detected in drinking water, so that it can be reliably quantified by most labs at below 1 ppb, the level at which it may pose a health risk.

- **Water Systems Should be Honest With Consumers about Arsenic Levels and Risks.** It is in public water systems□ best long-term interest to tell their customers about arsenic levels in their tap water and the health implications of this contamination. Only when it is armed with such knowledge can the public be expected to support funding and efforts to remedy the problem.

- **Water Systems Should Seek Government and Citizen Help to Protect Source Water.** Water systems should work with government officials and citizens to prevent their source water from being contaminated with arsenic.

- **Water Systems Should Treat to Remove Arsenic, and Government Funds Should be Increased to Help Smaller Systems Pay for Improvements.** Readily available treatment technology can remove arsenic from tap water, at a cost that is reasonable ($5 to $14 per month per household) for the vast majority of people (87 percent) served by systems with arsenic problems. Very small systems serving a small fraction of the population drinking arsenic-contaminated water, however, will often be more expensive to clean up per household. Assistance to such systems should be a high priority for drinking water funds such as the SRF and USDA's Rural Utility Service programs. The SRF should be funded at at least $1 billion per year to help systems with arsenic problems.

- **EPA Should Improve its Arsenic, Geographic Information, and Drinking Water Databases.** EPA should upgrade its Safe Drinking Water Information System to include and make publicly accessible all of the arsenic and unregulated contaminant

for source water protection, developing targeted and well-documented rules, and for other purposes.

Note

4. The Association of California Water Agencies and the American Water Works Association have charged the EPA has *underestimated* national arsenic treatment costs. However, EPA has responded in detail to these allegations and thoroughly rebutted these arguments.

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Arsenic and Old Laws

A Scientific and Public Health Analysis of Arsenic Occurrence in Drinking Water, Its Health Effects, and EPA's Outdated Arsenic Tap Water Standard

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The bulk of this paper, except the arsenic occurrence data and maps, was prepared by Dr. Paul Mushak as a pro bono professional courtesy to the Natural Resources Defense Council, without remuneration and in the interest of public health. It contains Dr. Mushak's independent analysis of key issues related to drinking water arsenic and human health and its critical conclusions about the inadequacy of current arsenic regulation and the need for the much lower indicated standard. The author gratefully acknowledges the editorial help of Betty Mushak, co-principal, PB Associates. The survey of arsenic levels in the drinking water of Americans and the maps of arsenic occurrence were prepared using EPA's 25-state arsenic database by Dr. Matthew McKinzie of NRDC. Erik Olson assisted in this data analysis, and thanks Anne, Chris, and Luke for their support in completing this project.

This report would not have been possible with the support of NRDC's more than 400,000 members. NRDC also thanks The Henry Philip Kraft Family Memorial Fund of The New York Community Trust, The McKnight Foundation, and Town Creek Foundation, Inc. for supporting our work on drinking water.

About the author

Paul Mushak, Ph.D., is a toxicologist and health risk assessment specialist working in the area of toxic environmental metals. He is a co-principal in PB Associates, Durham, NC, and is a visiting professor of pediatric toxicology and environmental health at the Albert Einstein College of Medicine in New York City. His work examining arsenic and other toxic substances spans almost 33 years. He has authored and co-authored numerous scientific publications in metals and served in numerous advisory roles on the health effects of arsenic and other elements with federal, state, international, and independent scientific agencies. He is a member of many scientific societies, including the Society of Toxicology. He served as a member of several National Academy of Sciences committees on metal contaminants and has testified twice before Congress on child environmental health matters. He was a principal co-author of the Environmental Protection Agency's 1984 health assessment document for arsenic, and a member of the external advisory panel of experts for EPA's 1988 special report on arsenic risk assessment issues. Dr. Mushak also chaired the 1995-1996 peer review panel evaluating EPA's report to Congress on hazardous air pollutants (HAPs) from fossil-fueled power plants. Arsenic was one of the key contaminants for HAP evaluation in that EPA report.

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APPENDIX A
List of Public Water Systems in Which Arsenic Was Found in the 25 States Reporting Data

Important note regarding arsenic levels in individual water systems listed in this report

The information on arsenic levels in public water systems included in the NRDC report *Arsenic and Old Laws* is derived from the U.S. Environmental Protection Agency's (EPA) 25-state arsenic database, which includes samples taken from 1980 to 1998. NRDC has not independently verified these data, which EPA collected from state drinking water program officials, and compiled into the 25-state arsenic database. Additional sampling may have been completed for some water systems after the EPA database was compiled. To verify information on all sampling completed to date for a public water system, contact your state drinking water program (call EPA's drinking water Hotline at 800 426-4791 for state contacts) or your water system.

Corrections: Because of an error in data reporting by the state of California, in the print version of this report and the earlier online version, Alameda County Water District, City of Antioch Water Department, and City of Santa Clara Water and Sewer Utilities were incorrectly included in charts identifying water systems with high average arsenic levels. NRDC has been informed that the monitoring results reported to the state of California by the City of Milpitas, which the state then reported to US EPA (and ultimately were reported by NRDC based on EPA's database), were for emergency wells not currently in use. This information was not indicated in EPA's database. The City of Milpitas has provided information indicating that the water used by the City of Milpitas has been consistently below 2 parts per billion (ppb).

How to download the chart(s)

Appendix A is posted in downloadable spreadsheet form. We've provided the information as one master chart, and then broken it up into 25 individual state charts.

These charts have been saved as "comma delimited files," a format that can be read by most spreadsheet programs and requires the least possible download time. To download, click on any file. A new browser window will open and display a document with many rows of text and numbers, separated by commas. Under your browser's File menu, select Save As and save the file, retaining the .csv extension. Open the file in your spreadsheet program.

The master chart is also available as a zipped Excel 5.0/95 Workbook file.

How to read the chart(s)

Because of the limitations of this file type, you may need to widen the columns in order to read the chart easily. To do this: When you open the chart some of the column headings will be obscured by text displayed at the top. Click into box A4 to clear the display. Then, with your mouse in the row of gray column labels at the top of the chart (A, B, C, etc.) rest it on the line between any two columns until the cursor becomes a black cross. Double click to expand the column. (Don't expand column A -- lengthy text in the first two rows will make the column too wide.)

Those column headings that may not be self-explanatory are explained below:

D. "Population Served" is the average number of people who drank water from the water system during the time the sampling was done.

E. "Low Est. of Average Arsenic Level (ppb)" is a very conservative (that is, low) estimate of the average arsenic concentration, stated in parts per billion (ppb), in the system's water over the period for which data were collected by the system. EPA collected data for 1980-1998, though data were not available from all systems for this full period. The low estimate assumes that when arsenic was not reported as detected, there was absolutely no arsenic in the water at that time, even if the limit of detection was high (for example, 10 ppb), and even if other tests showed that arsenic was present in the water at levels somewhat below the previous reporting limit.

F. "Best Estimate of Average Arsenic Level (ppb) is what we believe is the most reasonable estimate of the average arsenic level in the system's tap water, based on the

G. "# Samples in Which Arsenic Was Detected" lists the number of tests for arsenic in the system's water that found arsenic, according to the data in EPA's database.
H. "# of Samples in Which Arsenic Was Not Detected" lists the number of tests for arsenic in the system's water that did not find arsenic, according to the data in EPA's database.
I. "Qualifier for Minimum Level" includes two possible qualifiers for the minimum level in the next column: it can include a less than symbol ("<"), in which case the qualifier means that arsenic was not detected, with the stated detection limit. Thus, a "<" symbol in the qualifier column, followed by a 5 in the "Minimum Level Found" column, means that the minimum level of arsenic reported for the system was "less than 5 ppb."
J. "Min. Level Found" means the lowest level of arsenic reported for the system in the EPA database. If the lowest level found was a nondetect, it will be listed as <[the reporting limit]," as noted in the previous definition.
K. "Max. Level Found" means the highest level of arsenic reported for the system in the EPA database.
L. "Date Max. Level Found" means the date that the highest level of arsenic was found in the EPA database.
M. "Most Recent Sample in EPA Database (ppb)" means the level of arsenic found, in parts per billion, in the most recent arsenic test reported for that system in EPA's database.
N. "Date of Most Recent Sample in EPA Database" means the date that the most recent sample reported in the EPA database was taken.

The following information was provided by the EPA and describes its 25-state arsenic database and conventions applied to the database:

Arsenic occurrence and exposure database description (10/19/99)
This database contains arsenic compliance monitoring data from ground and surface water community water systems in 25 States (monitoring conducted to comply with the current 50 ppb arsenic standard). Some States also provided data from non-transient, non-community water systems (NTNCWS). EPA's Office of Ground Water and Drinking Water has received this data from various sources, including States, associations, and other EPA offices. EPA has compiled the data into a single uniform format to support development of national occurrence and exposure distributions of arsenic in public ground water and surface water supplies. Below is the list of the general data conventions that were applied to the data to condition them for EPA's initial analysis. EPA will be applying additional data conventions and further manipulating the data in order to develop the national occurrence and exposure estimates, to support the arsenic in drinking water regulation proposal (January 1, 2000). In addition, these data conventions may change as EPA analyzes the data further.
Data conventions applied to the state data
1. Deleted all observations with dates before 1980, and one observation dated 2010.
2. Deleted observations with no public water supply identifier (PWSID).
3. Deleted observations from purchased water systems or inactive water systems.
4. Arsenic values reported as "zero" or non-detect ("ND") were considered to represent an analytical result below the reporting limit. If the state did not disclose the reporting limits for the samples, reporting limits were assigned based on where the majority of the lowest measured results clustered. This change was made in only two States, Alabama and Oregon.
5. Deleted samples that were non-detects with reporting limits greater than 10 ppb (e.g., <20 ppb, <50 ppb).
6. Matched PWSIDs to EPA's Safe Drinking Water Information System (SDWIS) for population served, system type, source type, system name, etc. If State had provided this information and there was a discrepancy with SDWIS, used SDWIS information for consistency.
7. Missouri reported only "detect" results to EPA. EPA's contractor contacted the Missouri Department of Health, which provided PWSIDs for all systems that monitored but had no arsenic detects for the same time period of arsenic data submitted (1/12/95-9/3/97). For each of these systems, EPA added a "non-detect" observation at the reporting limit of 1 ppb. These data were combined with the MO positive results.

For additional information on the data and how it was collected and compiled, the health risks related to arsenic in drinking water, how NRDC analyzed the data and calculated our estimates, and our conclusions and recommendations, refer to the text of this report.

Download chart(s)

Appendix A master file
Comma delimited file (751K)
Zipped Excel 5.0/95 Workbook file (543K)

Individual charts for the 25 states that reported data

Alabama	Montana
Alaska	Nevada
Arizona	New Hampshire
Arkansas	New Jersey
California	New Mexico
Illinois	North Carolina
Indiana	North Dakota

Kansas
Maine
Michigan
Minnesota
Missouri
Oklahoma
Oregon
Texas
Utah

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Table 3
46 Largest Water Systems with Average Arsenic Levels Over 5 ppb (Ranked by Largest Population First)

Note: To print portions of this chart, in the Print dialogue box choose Properties and Paper and set to Legal and Landscape and click OK; under Print Range choose "from 1 to 1" and click OK (this will print one page and lock in settings); then use Print Preview to determine which page(s) to print.

Natural Resources Defense Council, February 2000.
Based on EPA's 25-State Arsenic Database of Samples Taken and Reported to States from
Contact Your Water System or State for All Sample Results.

Rank	Water System Name	State	County	Population Served	Low Est. of Average Arsenic Level (ppb)	Best Est. of Average Arsenic Level (ppb)	# Samples in Which Arsenic Was Detected	# S in A V D
1	LOS ANGELES-CITY, DEPT. OF WATER & POWER	CA	LOS ANGELES	3600000	4.2	**6.9**	92	
2	PHOENIX MUNIC WATER SYS	AZ	MARICOPA	1000000	4.6	**5.0**	312	
3	EL PASO WATER UTILITIES-PUB SERV B	TX	EL PASO	620000	6.6	**6.8**	42	
4	SOUTHERN NEVADA WATER SYSTEM	NV	CLARK	500000	5.0	**5.0**	1	
5	ALBUQUERQUE WATER SYSTEM	NM	BERNALILLO	417279	14.1	**14.2**	188	
6	MESA, MUNIC WATER DEPT.	AZ	MARICOPA	350000	7.0	**9.5**	94	
7	CORPUS CHRISTI CITY OF	TX	NUECES	270000	6.5	**6.5**	5	
8	STOCKTON EAST WATER DISTRICT	CA	SAN JOAQUIN	250000	2.2	**6.1**	4	
9	RIVERSIDE, CITY OF	CA	RIVERSIDE	245000	2.3	**5.4**	49	
10	SCOTTSDALE, MUNIC WATER	AZ	MARICOPA	174170	10.0	**11.1**	149	
11	GLENDALE MUNIC WATER CC	AZ	MARICOPA	150000	5.1	**5.9**	45	
12	KALAMAZOO	MI	KALAMAZOO	150000	5.5	**5.5**	13	
13	SAN BERNARDINO CITY	CA	SAN BERNARDIN	137738	3.1	**6.2**	11	
14	CHANDLER, MUNIC WTR DEPT	AZ	MARICOPA	132353	5.6	**7.6**	121	
15	DESERT WATER	CA	RIVERSIDE	125000	1.9	**5.3**	13	

	DEPARTMENT						
17	CWS - SALINAS	CA	MONTEREY	100300	2.0	**5.6**	16
18	DOMINGUEZ WATER CORP	CA	LOS ANGELES	100000	1.7	**6.0**	1
19	MIDLAND CITY OF	TX	MIDLAND	97458	10.8	**11.1**	7
20	LOS ANGELES CO WW DIST 4 & 34-LANCASTER	CA	LOS ANGELES	96073	12.0	**14.5**	82
21	NORMAN	OK	OK	80000	36.3	**36.3**	25
22	PEORIA, CITY OF	AZ	MARICOPA	74000	4.1	**6.3**	44
23	HOUSTON-GREENSPOINT	TX	HARRIS	72027	7.9	4	0
24	YORBA LINDA WATER DISTRICT	CA	ORANGE	70000	3.0	**5.9**	20
25	VICTORIA CITY OF	TX	VICTORIA	67353	11.2	**11.6**	3
26	GILBERT, TOWN OF	AZ	MARICOPA	67000	8.8	**9.3**	43
27	WATERFORD TOWNSHIP	MI	OAKLAND	66692	7.8	**7.8**	2
28	CITY OF LAKEWOOD	CA	LOS ANGELES	66000	13.9	**15.1**	39
29	ELSINORE VALLEY MWD	CA	RIVERSIDE	66000	2.2	**5.7**	15
30	BAKERSFIELD, CITY OF	CA	KERN	60720	1.5	**5.3**	14
31	MONTEREY PARK-CITY, WATER DEPT.	CA	LOS ANGELES	59000	5.3	**6.9**	15
32	GREAT FALLS CITY OF	MT	CASCADE	55097	7.8	**7.8**	11
33	CITY OF CERRITOS	CA	LOS ANGELES	53300	4.6	**6.2**	20
34	RANCHO CALIFORNIA WATER DIST	CA	RIVERSIDE	51672	1.7	**5.1**	41
35	CITY OF RIO RANCHO SEWER AND WASTEWATER SERV	NM	SANDOVAL	49999	12.1	**12.4**	39
36	PETALUMA, CITY OF	CA	SONOMA	49957	1.4	**5.0**	1
37	TURLOCK, CITY OF	CA	STANISLAUS	49500	5.1	**7.7**	36
38	CITY OF CHINO HILLS	CA	SAN BERNARDIN	49000	28.2	**30.2**	30
39	WEST SACRAMENTO, CITY OF	CA	YOLO	45000	5.5	**7.1**	29
40	MANTECA, CITY OF	CA	SAN JOAQUIN	44500	7.0	**9.6**	23
41	TRACY, CITY OF	CA	SAN JOAQUIN	44500	2.8	**6.5**	11
42	PORTSMOUTH, CITY OF	OH	SCIOTO	44004	1.6	**6.2**	1
43	FLAGSTAFF MUNICIPAL WATER	AZ	COCONINO	41200	3.6	**6.8**	15
44	MOORE	OK	OK	40300	12.3	**12.6**	59
45	SUN CITY WEST	AZ	MARICOPA	40000	14.4	**16.0**	19
46	ST. GEORGE CITY	UT	WASHINGTO	40000	8.0	**8.5**	41

*** Important note regarding arsenic levels in individual water systems listed in this rep**
public water systems included in the NRDC report *Arsenic and Old Laws* is derived from the (EPA) 25-state arsenic database, which includes samples taken from 1980 to 1998. NRDC

for state contacts) or your water system.

Corrections: Because of an error in data reporting by the state of California, in the print ver version, Alameda County Water District, City of Antioch Water Department, and City of San incorrectly included in charts identifying water systems with high average arsenic levels.

NRDC has been informed that the monitoring results reported to the state of California by th reported to US EPA (and ultimately were reported by NRDC based on EPA's database), we This information was not indicated in EPA's database. The City of Milpitas has provided infc City of Milpitas has been consistently below 2 parts per billion (ppb).

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Table 4
Highest Average Arsenic Levels in Water Systems Serving over 10,000 People (Ranked by Largest Population First)

Natural Resources Defense Council, February 2000.
Based on EPA's 25-State Arsenic Database of Samples Taken and Reported to States from
Contact Your Water System or State for All Sample Results.

Rank	Water System Name	State	County	Population Served	Low Est. of Average Arsenic Level (ppb)	Best Est. of Average Arsenic Level (ppb)	# Sam in W Arse Was Dete
1	OKLAHOMA UNIVERSITY	OK	OK	22738	78	78	
2	HANFORD, CITY OF	CA	KINGS	37000	51	51	
3	NORMAN	OK	OK	80000	36	36	
4	ANDREWS CITY OF	TX	ANDREWS	11061	35	35	
5	YUKON	OK	OK	20000	35	35	
6	CITY OF CHINO HILLS	CA	SAN BERNARDIN	49000	28	30	
7	ARVIN COMMUNITY SERVICES DIST	CA	KERN	10700	30	30	
8	WEATHERFORD	OK	OK	10400	29	29	
9	CALIFORNIA MENS COLONY	CA	SAN LUIS OBIS	15000	23	26	
10	US ARMY FORT IRWIN	CA	SAN BERNARDIN	17000	24	25	
11	CORCORAN, CITY OF	CA	KINGS	17560	23	23	
12	DELANO, CITY OF	CA	KERN	31235	22	23	
13	INDIAN WELLS VALLEY W.D.	CA	KERN	32630	21	23	
14	NELLIS AIR FORCE BASE AREA I	NV	CLARK	18100	21	21	
15	LEMOORE, CITY OF	CA	KINGS	15806	21	21	
16	M.D.O.T-GRAYLING REST 1&2,R403	MI	CRAWFORD	12000	20	20	
17	AZ WATER CO-APACHE JCT S	AZ	PINAL	34900	16	17	
18	AZ WATER CO-CASA GRANDE	AZ	PINAL	36500	16	17	
19	SUN CITY WEST	AZ	MARICOPA	40000	14	16	
20	NEW MEXICO UTILITIES, INC.	NM	BERNALILLO	14000	15	15	
21	CITY OF LAKEWOOD	CA	LOS ANGELES	66000	14	15	
22	AVONDALE, CITY PUBLIC WO	AZ	MARICOPA	22000	13	15	
23	LOS ANGELES CO WW DIST 4 & 34-LANCASTER	CA	LOS ANGELES	96073	12	15	
24	ALBUQUERQUE WATER SYSTEM	NM	BERNALILLO	417279	14	14	
25	HILLCREST WATER COMPANY 1,2,3,4	CA	SUTTER	10062	13	13	
26	SCWC - ARTESIA	CA	LOS ANGELES	35731	11	13	

28	MOORE	OK	OK	40300	12	13	
29	ELK GROVE WATER WORKS	CA	SACRAMENTO	23000	12	13	
30	MOUNDS VIEW	MN	RAMSEY	12700	12	13	
31	CITY OF RIO RANCHO SEWER AND WASTEWATER SERV	NM	SANDOVAL	49999	12	12	
32	PARADISE V WATER CO-AM W	AZ	MARICOPA	12000	12	12	
33	CITY OF ELKO	NV	ELKO	10000	12	12	
34	EAST NILES CSD	CA	KERN	21500	11	12	
35	VICTORIA CITY OF	TX	VICTORIA	67353	11	12	
36	SCWMD LAGUNA/VINEYARD	CA	SACRAMENTO	20259	11	12	
37	HCO MUD NO 53	TX	HARRIS	19227	12	12	
38	WOODBURN, CITY OF	OR	MARION	15225	11	11	
39	SCOTTSDALE, MUNIC WATER	AZ	MARICOPA	174170	10	11	
40	MIDLAND CITY OF	TX	MIDLAND	97458	11	11	
41	TRUCKEE-DONNER PUD, MAIN	CA	NEVADA	14200	9	11	
42	BELLFLOWER - SOMERSET MWC	CA	LOS ANGELES	24000	8	11	
43	GALT, CITY OF	CA	SACRAMENTO	12000	9	11	
44	JEFFERSON CO CONS PWSD C1	MO	MOJEFFERSON	30000	10	10	
45	BEALE AIR FORCE BASE	CA	YUBA	10000	5	10	
46	MANTECA, CITY OF	CA	SAN JOAQUIN	44500	7	10	
47	MESA, MUNIC WATER DEPT.	AZ	MARICOPA	350000	7	10	

*** Important note regarding arsenic levels in individual water systems listed in this rep**
systems included in the NRDC report *Arsenic and Old Laws* is derived from the U.S. Enviro
database, which includes samples taken from 1980 to 1998. NRDC has not independently v
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NRDC has been informed that the monitoring results reported to the state of California by th
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Figure 1
NATIONAL ARSENIC OCCURRENCE MAP

This map is intended to show the general areas that are hardest hit by the highest levels of arsenic. However, to determine whether arsenic has been found in a particular public water system, according to data reported to the U.S. Environmental Protection Agency, refer to the table of water systems reported in Appendix A. The map cannot be used by itself to identify whether a particular water system has an arsenic problem, because often there are several water systems located immediately adjacent to each other, and the map was generated at a scale that cannot be used to identify precisely which water system contains a given level of arsenic.

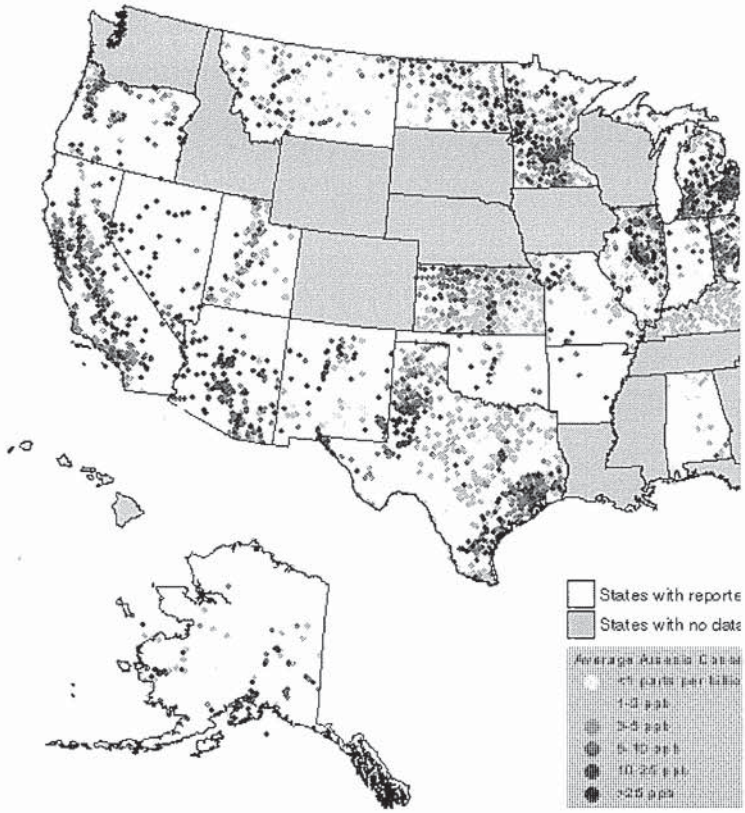

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Table 5
50 Public Water Systems Of Any Size With Highest Average Arsenic Levels (Ranked by Best Estimate of Average Concentration)

Note: To print portions of this chart, in the Print dialogue box choose Properties and Paper and set to Legal and Landscape and click OK; under Print Range choose "from 1 to 1" and click OK (this will print one page and lock in settings); then use Print Preview to determine which page(s) to print.

Natural Resources Defense Council, February 2000.
Based on EPA's 25-State Arsenic Database of Samples Taken and Reported to States fror
Contact Your Water System or State for All Sample Results.

Rank	Water System Name	State	Population Served	Low Est. of Average Arsenic Level (ppb)	Best Est. of Average Arsenic Level (ppb)	# Samples in Which Arsenic Was Detected	# o Sar in \ Ars Wa Det
1	PAUG VIK, INC. INLET SALMON	AK	25	220.0	**220.0**	1	
2	J TRAILER PARK	CA	25	210.0	**210.0**	2	
3	DATELAND VINEYARD LABOR	AZ	75	195.0	**195.0**	4	
4	SOUTHWEST SPORTS PLEX	TX	300	162.0	**162.0**	1	
5	TOLAS PARK	NV	109	150.0	**150.0**	1	
6	SAN YSIDRO WATER SUPPLY SYSTEM	NM	300	140.3	**140.3**	7	
7	HCO FACILITY & PROPERTY MANAGEMENT	TX	3000	138.0	**138.0**	1	
8	MONTGOMERY MOBILE HOME PARK	NV	150	130.0	**130.0**	1	
9	DSET LABORATORIES WATER	AZ	56	125.3	**125.3**	3	
10	ALASKA RAINBOW LODGE	AK	26	120.0	**120.0**	1	
11	VISTA HERMOSA MHP	AZ	180	118.2	**118.2**	27	
12	MOUNTAIN HOME ESTATES ASSN	NH	500	107.9	**107.9**	10	
13	ROOSEVELT LAKE RV PARK	AZ	200	93.2	**93.7**	18	
14	LKSD NAPAKIAK HS & ELEM	AK	124	93.3	**93.3**	3	
15	WYNRIDGE CONDOMINIUM	NH	58	92.3	**93.2**	2	

17	MOUNT WESKE ESTATES MUTUAL WATER COMPANY	CA	71	69.4	**69.4**	5	
18	WESTHAVEN MOBILE COURT	MI	193	89.0	**89.0**	1	
19	FALLON NAVAL AIR STATION	NV	4850	85.0	**85.0**	1	
20	WHY UTILITY CORP	AZ	960	80.8	**81.4**	14	
21	LKSD NAPASKIAK Z J WILLIAMS SC	AK	121	79.7	**79.7**	8	
22	OKLAHOMA UNIVERSITY	OK	22738	78.5	**78.5**	20	
23	NAPASKIAK WATER SYSTEM	AK	367	77.5	**78.0**	4	
24	SABROSA WATER CO NEW RIV	AZ	270	77.4	**77.6**	24	
25	SEVENTH DAY ADVENTIST SCHOOL	MI	50	76.0	**76.0**	1	
26	MITCHELL'S CORNER WATER SYSTEM	CA	32	73.0	**73.0**	1	
27	FLYING A TRAILER PARK	NV	25	73.0	**73.0**	1	
28	BREEZY PINES WATER INC-L	AZ	50	71.5	**71.5**	2	
29	OLIVET ELEMENTARY SCHOOL	CA	450	71.1	**71.1**	11	
30	CAROLINA FOREST S/D	NC	360	69.4	**69.6**	6	
31	FOUNTAIN TRAILER PARK WATER	CA	40	69.0	**69.0**	1	
32	PRAIRIE VIEW ESTATES MHP	IL	120	67.1	**67.1**	12	
33	BADGER DEN	AK	150	66.1	**66.1**	7	
34	KOUNTRY MANOR MOBILE HOME PARK	MN	75	65.8	**65.8**	18	
35	CITY OF CHENEY	KS	1560	65.1	**65.1**	6	
36	BRUNI RURAL WATER SUPPLY CORP	TX	363	65.0	**65.0**	2	
37	CORAL GABLES MOTEL	MI	25	64.0	**64.0**	1	
38	WINDEMERE POINT S/D	NC	25	63.0	**63.4**	3	
39	CAVE CREEK WATER	AZ	1300	63.0	**63.3**	38	
40	PHILADELPHIA WATER SYSTEM	AZ	75	62.3	**62.3**	3	
41	CAMP VERDE WTR SYSTEM	AZ	1500	58.3	**58.5**	27	
42	LKSD TUNTUTULIAK ANGAPAK SC	AK	101	58.2	**58.3**	8	

44	BYRON WOODS SBDV	IL	210	56.3	56.3	13	
45	FERNLEY UTILITIES	NV	5950	56.0	**56.0**	1	
46	LKSD KWETHLUK HS & ELEM	AK	225	55.5	**55.6**	7	
47	LAMCREST ENTERPRISES	AZ	40	55.2	**55.2**	17	
48	KENAI WILDERNESS LODGE	AK	25	54.0	**54.0**	1	
49	SOUTH MAINE ADULT MHP	NV	168	54.0	**54.0**	1	
50	CEDAR LODGE MOTEL/SUPERIOR TRL	NV	100	53.5	**53.5**	2	

*** Important note regarding arsenic levels in individual water systems listed in this re**
water systems included in the NRDC report *Arsenic and Old Laws* is derived from the U.S.
state arsenic database, which includes samples taken from 1980 to 1998. NRDC has not ir
collected from state drinking water program officials, and compiled into the 25-state arsenic
completed for some water systems after the EPA database was compiled. To verify informa
public water system, contact your state drinking water program (call EPA's drinking water h
water system.

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ATTACHMENT 12

EPA aims to cut levels of arsenic in well water

[1 3 Edition]

The San Diego Union - Tribune - San Diego, Calif.
Author: Steve LaRue
Date: Jun 5, 2000
Start Page: B.1
Section: LOCAL
Text Word Count: 1549

Document Text

For text of mac-produced charts, see microfilm.

Residents of several outlying areas in San Diego County and across the nation may be paying an unseen price for their rural lifestyles - - increased cancer risk -- health experts say.

The cause: the classic poison arsenic, a metal present in deep rocks, particularly in desert and mining areas. Underground water in these areas dissolves the poison and delivers low levels of it into humans who drink it.

The federal Environmental Protection Agency is proposing to shrink the limit on arsenic in drinking water to one-tenth the current limit, to five parts per billion from 50.

That would mean more stringent water testing requirements at a dozen water systems in this region that rely at least partly on well water and serve communities such as Borrego Springs, Camp Pendleton, Escondido, Jacumba, Poway, La Mesa and El Cajon.

Larger systems, such as the La Mesa-based Helix Water District, already have treatment plants that remove this and other contaminants. If arsenic levels are found to exceed the new health standard in smaller water districts, the cost to users to build treatment works could be considerable because it would be spread among relatively few customers.

The EPA says the proposed health standard could lower cancer risks for 22.5 million Americans, but could require customers of 2,000 to 2,500 small water districts in California, mostly in Southern California, to endure higher water rates to finance new treatment systems.

Nationwide, customers of 6,000 to 7,000 small water systems could face higher costs, the EPA says.

"A lot of systems that use wells are going to have to look more closely for arsenic than they have before," said Bruce Macler, chief drinking water toxicologist for the EPA's western regional office in San Francisco.

"I wouldn't be surprised if 30 to 40 percent of these systems have to do something," he said. "I am sure some of the systems in San Diego County will be impacted."

One part per billion, or ppb, is equivalent to about one drop of water in a large high school swimming pool, or one second in about 32 years.

The EPA's move to tighten the arsenic standard follows a 1999 study by the National Research Council. The existing standard is based on a level set in the early 1940s before arsenic was known to cause cancer. The EPA says it could pose long-term cancer risks in some areas of greater than one case of cancer per 100 people who drink water containing the maximum arsenic levels.

That is, one of every 100 people who drink water with 50 ppb of arsenic would be expected to develop one type of cancer during his or her life.

This is a much higher risk level than the one-per-million the EPA tolerates as a maximum for other drinking water contaminants.

The report concludes: "The current (standard) for arsenic in drinking water does not achieve the EPA's goals for public health protection and, therefore, requires downward revision as promptly as possible."

Water industry trade groups say a less strict standard, such as 10 parts per billion, might be more appropriate, and also a lot less expensive.

"We definitely agree that the standard has to come down, but we are a little apprehensive about what the number should be," said Krista Clark, regulatory specialist for the 442-member Association of California Water Agencies.

Costs could reach $100 per household per year in rural areas, she said, and should not be imposed until there is more scientific consensus on what the standard should be.

These charges, she warned, would reflect the high costs of building and maintaining water treatment works in rural areas where there are not many water customers to share those costs.

Meanwhile, a key environmental group is urging the EPA to make the new arsenic standard even more strict.

"We have called on the EPA to adopt a standard no higher than 3 ppb," said Erik Olson, senior attorney for the Natural Resources Defense Council, or NRDC.

"Clearly, it would be a substantial improvement to go from 50 ppb down to 5 ppb, but the total cancer risk at 5 ppb is still one in 1,000, which is far higher than EPA ever accepts (from other contaminants) in drinking water," he said.

Drinking arsenic-laced ground water over decades has been observed in other countries to increase the incidence of cancers that attack a variety of organs, from the bladder to the lungs, and to contribute to heart illness, federal officials say.

Studies of parts of India where arsenic levels approach 500 ppb indicate that 10 percent of the people who drink the water for long periods develop cancer, said the EPA's Macler.

How many San Diego County residents, or other Americans, may be at risk? Without standardized tests and monitoring procedures, experts say this is difficult to determine. For example, some testing procedures register a "not detectable" reading when the arsenic level is lower than 10 ppb or 20 ppb, experts say.

The vast majority of Southern California's 17 million water consumers, including most urban and suburban dwellers in San Diego County, will not be affected because most of their water comes from mountain snowpacks and rainfall captured as it flows down distant rivers.

Even when some of the wells in these large "surface water" systems contain high arsenic levels, their water is vastly diluted, then treated to remove this and other contaminants.

"The highest arsenic value we have seen in the last year is slightly over 2 ppb, so we are slightly over half of the proposed limit," said John Chaffin, the city of San Diego's water quality superintendent.

The city does draw water from a single well, in El Cajon, where arsenic levels were recorded at 10.2 ppb in 1994. But the water is treated to remove the arsenic and then greatly diluted before it is delivered to customers, Chaffin said.

The existing arsenic standard applies to so-called community water systems and larger systems. A community system is one with at least 15 service connections that supplies at least 25 people throughout the year.

The EPA is proposing to extend the new arsenic standard to include systems that regularly serve 25 or more people at least six months out of the year.

These could be small water companies or special water districts. Neither the existing nor the proposed arsenic standard would apply to so-called "transient" systems, which people do not use continually, such as wells supplying water for rural restaurants or gas stations. Private wells supplying farms and rural homes would not fall under the standard, either.

Private well owners can have their water tested for arsenic and can remove it by using filters containing iron oxide or aluminum oxide.

The San Diego County Department of Health Services monitors arsenic testing at community water systems but refused to disclose which of them has tested above 5 ppb for arsenic. A spokesman said the reason is that the

proposed standard has not been approved, and specific testing procedures have not been identified by the State Department of Health Services.

"We are expecting some kind of guidance from the state as to how to implement the new standard," but there is little doubt that several systems in San Diego County will exceed it, said Frank Gabrian, supervising environmental health specialist.

Counties submit well test results to the states, and states report them to the federal government. Some of these results were obtained under the Freedom of Information Act by the NRDC and posted on the group's Web site (http://www.nrdc.org).

But the results may not tell the whole story.

They suggest, for example, that 1,200 or more residents of Borrego Springs consumed well water in 1997 that contained an average level of 5.6 ppb of arsenic, and that well arsenic concentrations there reached a peak of 10.2 ppb in 1988.

But Linden Burzell, chief engineer for the Borrego Water District, said he is not familiar with such test results.

"We measured the wells in 1998 and have taken hundreds of different samples, and we will be doing this again next year," Burzell said. "All of our 12 wells show that arsenic is undetectable except for one well, where it is at 2 ppb, so arsenic levels in the Borrego Valley aquifer are very low."

The NRDC data also indicate arsenic levels that might exceed the new standard in wells in Jacumba and at Camp Pendleton.

State and county officials said new compliance and testing rules will be needed to tell which water districts comply with the new arsenic standard. The state would be expected to issue these rules about 18 months after a new federal standard is approved.

Credit: STAFF WRITER

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Abstract (Document Summary)

The EPA's move to tighten the arsenic standard follows a 1999 study by the National Research Council. The existing standard is based on a level set in the early 1940s before arsenic was known to cause cancer. The EPA says it could pose long-term cancer risks in some areas of greater than one case of cancer per 100 people who drink water containing the maximum arsenic levels.

They suggest, for example, that 1,200 or more residents of Borrego Springs consumed well water in 1997 that contained an average level of 5.6 ppb of arsenic, and that well arsenic concentrations there reached a peak of 10.2 ppb in 1988.

1 PIC | 3 CHARTS | 1 DIAGRAM; Caption: 1. Marc Hall, a San Diego Water Department chemist, diluted a sample from Otay Lakes. The EPA has proposed lowering the limit on arsenic in drinking water. 2,3,4,5. Arsenic in drinking water (B-3) 2. The element arsenic occurs naturally in the soil. In many areas, it dissolves into the public water supply. (B-3) 3,4. Long-term exposure hazards (B-3) 5. Web sites for more information (B-3); Credit: 1. Earnie Grafton/ Union-Tribune 2,3,4,5. SOURCES: U.S. Environmental Protection Agency; California Department for Health Services; Natural Resources Defense Fund; Knight Ridder/Tribune | UNION-TRIBUNE

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ATTACHMENT 13

PRESS RELEASE

Confidential Papers Show Exxon Hand in White House Move to Oust Top Scientist from International Global Warming Panel

April 03, 2002

MEDIA CONTACTS

Jon Coifman, 202-289-2404 or Elizabeth Heyd 202-289-2424

Oil Company Memo Calls for Dr. Watson's Dismissal; Administration Obliges

WASHINGTON (April 3, 2002) -- The Bush administration this week moved to oust a top scientific official targeted by ExxonMobil in a confidential memo to the White House. Bold language in the ExxonMobil papers released today by NRDC (the Natural Resources Defense Council) reflects a brazen, behind-the-scenes effort by the oil company and other energy giants to disrupt the principal international science assessment program on global warming.

Dr. Robert Watson, a highly respected atmospheric scientist, has been chair of the Intergovernmental Panel on Climate Change (IPCC) since 1996. Operating under United Nations auspices, the 2500-member expert panel provides policymakers around the world with rigorous, consensus-based assessments generally regarded as the most authoritative word on global warming and its causes.

Without formal announcement, the administration has decided to oppose Watson's appointment to a second term as IPCC chair, seriously damaging his prospects when representatives of more than 100 governments meet in Geneva April 17-20 to elect a new IPCC head.

The memorandum, obtained by NRDC from the White House Council on Environmental Quality under the Freedom of Information Act, shows that ExxonMobil began a secret campaign for Dr. Watson's removal in the first weeks of the Bush administration, and reveals ExxonMobil's intention to replace Watson and other key scientists with contrarians known for disagreeing with the prevailing consensus that man-made pollution is causing global warming.

In meetings this week with State Department officials, lobbyists for the coal industry, electric utilities, and automakers joined ExxonMobil's call to replace Watson.

"It's bad enough that ExxonMobil controls White House energy and climate policies," said Daniel Lashof, science director of the NRDC Climate Center. "Now they want to control the science too."

Under Watson's tenure, the IPCC last year produced its third comprehensive assessment of the state of climate science, concluding that "[t]here is new and stronger evidence that most of the warming observed over the last 50 years is attributable to human activities," and predicting that average global temperatures will rise between 3 and 10 degrees Fahrenheit by the end of the century -- conclusions reaffirmed last spring at White House request by the National Academy of Sciences.

In a letter yesterday to Undersecretary of State Paula Dobriansky, NRDC's Lashof said: "The industry effort to block the reappointment of Dr. Watson is a thinly veiled attempt to undermine the effectiveness of the IPCC as a body that produces high quality, objective scientific assessments. I urge you to reject this campaign and to give Dr. Watson the United States' strongest possible support."

The Natural Resources Defense Council is a national, non-profit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment. Founded in 1970, NRDC has more than 500,000 members nationwide, served from offices in New York, Washington, Los Angeles and San Francisco.

Additional Downloadable Materials for the Press

ExxonMobil Memorandum in PDF format, 232k.

NRDC letter to State Department in Microsoft Word format, 22k.

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Facsimile Cover Sheet

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Date/Time: 6 Feb 2001, 10:00 a.m.

Pages including Cover: 18

Regarding: *Bush Team for IPCC Negotiations*

Attached is a brief memo outlining the issues related to the on-going IPCC negotiations on the Third Assessment Report. I have also attached other material that may be useful to you.

I will call to discuss the recommendations regarding the team that can better represent the Bush Administration interests until key appointments and re-assessments are made.

Randy

Global Climate Science-Issues for 2001

A. Intergovernmental Panel on Climate Change (IPCC)

1. The IPCC is on schedule to issue in late September 2001 its Third Assessment Report (TAR), composed of three Working Group Reports on the science, impacts and mitigation of climate change and a Synthesis Report. The IPCC is headed by Robert Watson, an American who is also the chief science person at the World Bank (Director, Environment Dept.) Watson was hand picked by Al Gore and served in the Clinton/Gore White House Office of Science and Technology policy. His tenure at the IPCC ends with the completion of the TAR. However, he could be extended at an IPCC session this year or next.

During the Hague meeting in November, Watson presented a sneak preview of the Third Assessment Report with the following caveat " *None of the conclusions presented in this report are taken from the TAR, but are consistent with the draft conclusions, which are subject to change until final government approval and acceptance early next year.*" His statement belied his real intent, which was to get media coverage of his views before there was a chance for the process to challenge his personal agenda.

Issue: Can Watson be replaced now at the request of the U.S.?

The Working Group Reports are prepared by scientists, economists, engineers, and others, including some persons from industry and environmental organizations. **Each report includes a "Summary for Policy Makers" (SPM) that is approved by IPCC governments by consensus in a line-by-line review at a Working Group session** with the underlying report (approx. 1000 pages) accepted by the Group at that session.

In the case of the Working Group I report on science, the Group met in plenary in Shanghai, China on January 17-20, approved the SPM, and accepted the report. The US delegation (Moitke lead) was satisfied to raise no objections on the tone and content of the report. To avoid accountability to the Bush Administration, the meeting actually ran until 1:00 a.m. on January 21 which was exactly January 20, 12:00 noon in the U.S. The U.S. was represented by Clinton/Gore carry-overs with aggressive agendas:

1. State Department: **Jeff Moitke**, Deputy Director, Global Change Office, Oceans and International Environmental and Scientific Affairs (and Deputy Chief of Mission, Lesotho)

2. White House Office of Science and Technology Policy: **Rosina Bierbaum**, Associate Director, Environment,

3. White House U.S. Global Change Research Program: **Michael MacCracken**, Executive Director, National Assessment Coordination Office.

Global Climate Science-Issues for 2001

Bierbaum and MacCracken were both actively involved in the production of the US National Assessment that has been roundly criticized for its political and scientific bias. The National Assessment was driven by a political schedule to help the Gore campaign. Several controlled leaks were used to get maximum media attention since Congressional oversight forced a delay in the release of the report.

Issue: Have Bierbaum and MacCracken been removed from their positions of influence?

Issue: What was the U.S. position on the WG1 Report? Did it reflect the comments received?

While the SPM was written to highlight the "human fingerprint", it also states that: "Further research is required to improve the ability to detect, attribute and understand climate change, to reduce uncertainties, and to project future climate changes."

According to an AP story, Watson, in commenting on the report, which was released by the Group, but which has not yet been accepted by the full IPCC, said:

> "The United States is way off meeting its targets," said Watson. "A country like China has done more, in my opinion, than a country like the United States to move forward in economic development while remaining environmentally sensitive."

China, of course, has no commitments under the Kyoto Protocol and its greenhouse gas emissions are growing and will soon exceed those of the U.S.

2. **Working Group II is scheduled to meet on the "Impacts of Climate Change" in plenary in Geneva, Switzerland, from February 12-16.** Reportedly, the U.S. has submitted comments on the draft report by January 8, which was the deadline. Those comments have not been made public.

Issue: Who has reviewed those comments?

Issue: What is the U.S. position on the report?

Issue: Who will represent the U.S. at this meeting?

3. **Working Group III** is scheduled to meet on "Mitigation of Climate Change" in plenary in **Accra, Ghana, from February 28 to March 3.** Government comments on that draft report/SPM are due to be submitted by January 29.

Issue: Who has reviewed those comments?

Issue: What is the U.S. position on the report?

Issue: Who will represent the U.S.? What is U.S. position?

4. On **April 4-6, 2001**, the full IPCC is scheduled to meet in plenary in **Nairobi, Kenya**, to accept by consensus the results of the three Working Groups.

Issue: Will the U.S. revisit the Working Group I comments of the Clinton/Gore representatives?

Issue: Who will represent the U.S. and what will be the U.S. position?

Issue: Can this report be deferred until the US has provided updated input(30-45 days)?

5. **The last element of the TAR is the Synthesis Report (SR) that is still being drafted under Robert Watson's control.** A draft of the SR, including its SPM, is to be sent out for simultaneous expert and Government review and comment with a deadline of May 29. A second draft is scheduled to be given to Governments only for their review and comment on July 6 with a deadline of August 31. **The IPCC plenary will meet in London from September 24-29 to adopt/approve the Synthesis Report by consensus.**

Issue: Can this report be deferred at least 45 days?

Thereafter the entire TAR will be released(in time for political use at COP-7).

COP-6, held in The Hague last November, ended without finishing its work on implementation of the Kyoto Protocol and with an understanding that it would meet again in 2001, but with no date established. The SBI and SBSTA are scheduled to meet in Bonn, Germany, from May 21-June 1. Some Parties want COP-6 to reconvene during that time. **COP-7 is scheduled to meet October 29-November 9 in Marrakech, Morocco, together with the subsidiary bodies.**

Global Climate Science-Issues for 2001

Recommendations:

1. Restructure the U.S. attendance at upcoming IPCC meetings to assure none of the Clinton/Gore proponents are involved in any decisional activities.

a. Appoint **Dr. John Christy**, University of Alabama-Huntsville(Lead Author-Working Group I) as science lead for the balance of the IPCC process. Phone: 256.961.7763 This replaces Bierbaum and MacCracken.

b. Appoint **Dr. Richard Lindzen**, MIT,(Lead Author-Working Group I) as a co-lead to conduct an immediate review of the comments on the Working Group reports(I, II and III) and to review the US comments to be submitted(II, III). Phone: 617.253.2432

c. Detail **Dr. Joe Friday**, National Research Council-Board on Atmospheric Sciences and Climate(Coordinated the "Research Pathways for the Next Decade" report that the Clinton Admin tried to bury), to work with Christy/Lindzen. Phone: 202.334.3512

d. Detail someone from the State Dept to work under the direction of Christy/Lindzen for the "consensus negotiations". This replaces Moltke.

2. Request that the April 4-6 full IPCC meeting be deferred at least 30 days until a re-assessment of US input can be made.

3. Request that all action related to the Third Assessment Report is deferred until the IPCC process is complete (30-45 days). This must include the Watson release of the draft Synthesis Report.

4. Explore the possibility of asking Speaker Hastert to make Dr. Harlan Watson, Hse Science Committee, available to work with the team. Dr. Watson has been recommended for the Assistant Secretary of State for Oceans position.

ATTACHMENT 14

Los Angeles Times | ARTICLE COLLECTIONS

← Back to Original Article

The Nation

Charges Fly Over Science Panel Pick

April 04, 2002 | ELIZABETH SHOGREN | TIMES STAFF WRITER

WASHINGTON — The Bush administration is pushing for an engineer from India to take over the helm of an influential international science panel on global warming that is now headed by an American atmospheric chemist who has been criticized by the energy industry.

Energy lobbyists have accused Robert T. Watson, chairman of the Intergovernmental Panel on Climate Change, of promoting his own agenda. In a memo to the White House a year ago, a senior Exxon Mobil Corp. official urged the administration to push him out.

"Can Watson be replaced now at the request of the U.S.?" asks the memo, which was obtained from the White House through a Freedom of Information Act request by the Natural Resources Defense Council, an environmental group.

The council accuses the Bush administration of turning its back on solid science and bending to industry wishes by supporting Watson's challenger, Dr. Rajendra K. Pachauri. In an election later this month, the 100-plus member countries of the climate panel will have one vote each on the chairmanship.

"It's bad enough that Exxon Mobil controls White House energy and climate policies," said Daniel Lashof, science director of the NRDC Climate Center. "Now they want to control the science too."

Also promoting Watson's reelection are leading climate scientists such as Ralph J. Cicerone, chancellor of UC Irvine and chairman of a National Academy of Sciences panel that reviewed global warming issues for the Bush White House.

Bush administration officials said they decided to support Pachauri because his background as an engineer and an economist prepares him to determine the global implications of climate science. They said the administration also believes that a chairman from the developing world would signal that global climate change is a problem for the whole world, not just for wealthy nations.

Environmentalists and Watson say the administration's decision reflects its discomfort with having Watson on a prestigious platform for broadcasting to the world the seriousness of global climate change resulting from the burning of coal, gas, oil and other fossil fuels.

"There is new and stronger evidence that most of the warming observed over the last 50 years is attributable to human activities," the climate change panel concluded last year in its third comprehensive assessment under Watson's chairmanship.

"I've been hearing over the last month or two that a small vocal part of the energy industry has been putting a lot of pressure on the U.S. government not to reelect me," said Watson, who was the associate director for environment in the White House Office of Science and Technology during President Clinton's first term.

Watson said he believes he still has a good chance to win reelection. Officials from many countries have told him they will support his candidacy because of his ability to organize thousands of scientists to review documents and develop coherent analyses of the complicated problem.

Watson said he hopes the Bush administration does not believe energy lobbyists' claims that he advocates tough government regulations of industries that emit carbon dioxide, the major greenhouse gas produced from human activity.

"My advocacy is for truth in science--that we do get the very best scientists from around the world," Watson said. "The argument that I'm an advocate for regulations against the oil industry is incorrect."

President Bush's climate change policy calls on industry to voluntarily reduce carbon dioxide emissions.

White House spokesman Scott McClellan disputed the claim that the Exxon Mobil memo influenced the White House decision on the IPCC chairmanship. The memo "was faxed to an individual who had no involvement with IPCC leadership issues and took no action on the memo," he said.

Neither he nor any official provided by the Bush administration to comment on the issue flatly denied that industry influence played a role in the State Department's decision to side with Pachauri.

Energy industry lobbyists met Tuesday with State Department officials before the decision to support Pachauri was announced. But a Bush administration official said the decision already had been made.

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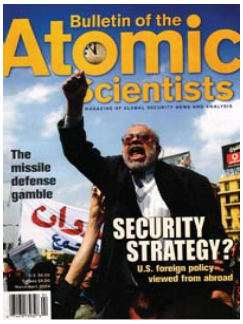
ATTACHMENT 15



Bulletin of the Atomic Scientists

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The protection paradox

Hans M. Kristensen, Matthew G. McKinzie & Robert S. Norris

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The protection paradox

by Hans M. Kristensen, Matthew G. McKinzie & Robert S. Norris

Who's kidding who? If you think a missile defense deployment will make the world safer, take a look at how the United States reacted to the Soviet missile defense of Moscow.

THE UNITED STATES PLANS TO begin deployment of a limited ballistic missile defense system at Fort Greely in Alaska and Vandenberg Air Force Base in California by the end of 2004. With 10 silo-based interceptors intended to shoot down long-range ballistic missiles, the system will serve as "a starting point for fielding improved and expanded missile defense capabilities later," according to the White House. The system is expected to grow to 20 silo-based interceptors in 2005, and up to 100 interceptors in the following years.

How will other nuclear powers respond? Some suggest that Russia might modernize its forces to be able to overwhelm the U.S. system and that China might improve its intercontinental ballistic missiles (ICBMs) to ensure the credibility of its deterrent. But the Bush administration insists this won't happen.

"Our missile defenses will be no threat to Russia," Douglas J. Feith, undersecretary of defense for policy, told the Senate Foreign Relations Committee in July 2001. Such U.S. defenses will not affect Russian capabilities, he said, so "there is no incentive for Russia to spend scarce resources to try to overcome them." And China, Feith claimed, "will continue [its] modernization whether or not we build missile defenses."

How can the Bush administration be so sure of how Russia or China will react? Its position is more wishful thinking than careful analysis. Had it bothered to examine how the United States itself reacted when faced with a Soviet missile defense system, it might have come to a different conclusion.

Documents recently declassified under the Freedom of Information Act (FOIA) reveal that in 1968 U.S. war planners sought to overwhelm Soviet defenses with enough nuclear firepower to kill tens of millions of people. The documents reveal that the United States considered all components of the Soviet anti-ballistic missile (ABM) system—missile interceptors, battle radars, and distant early warning radars—as high-priority targets for nuclear weapons.

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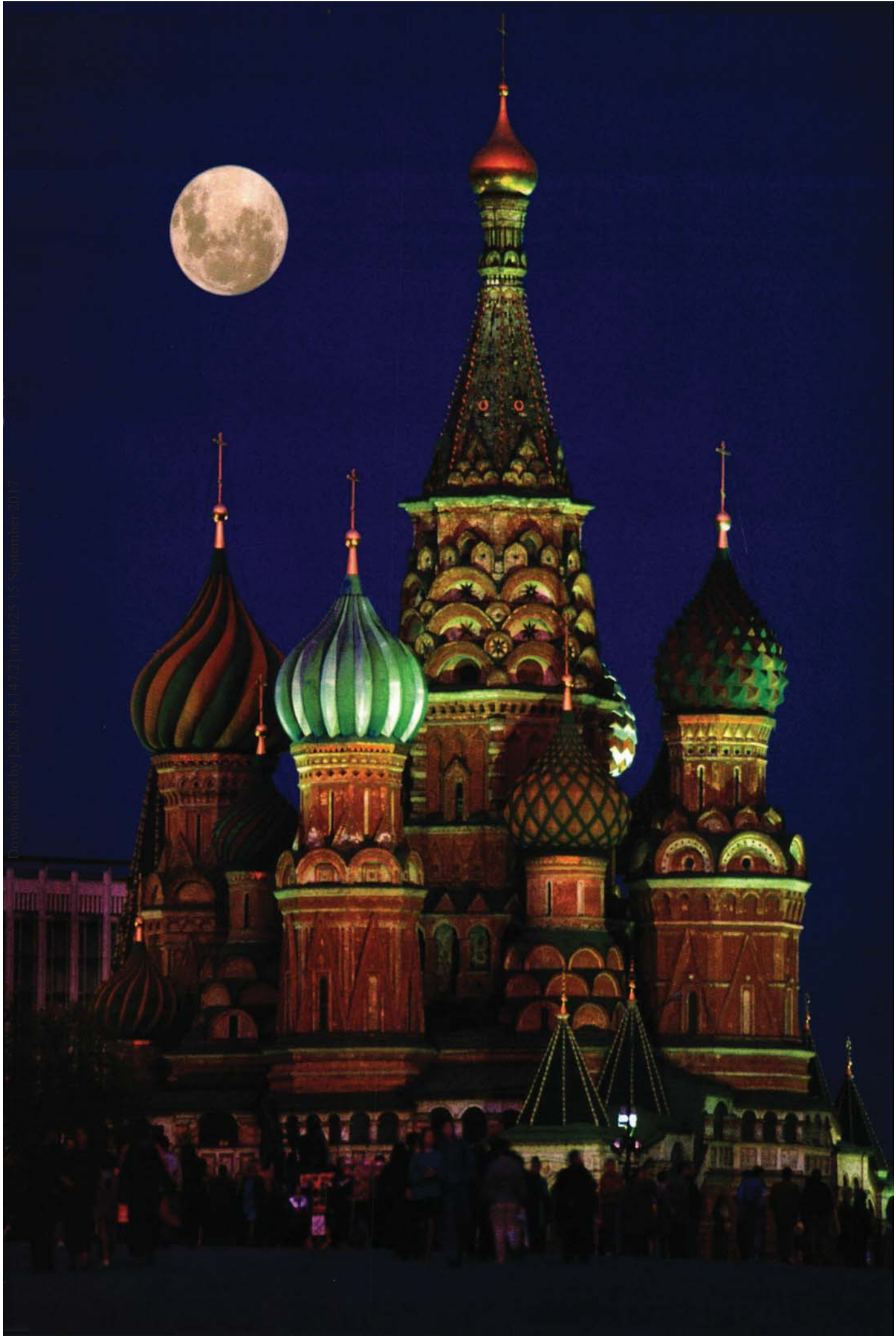

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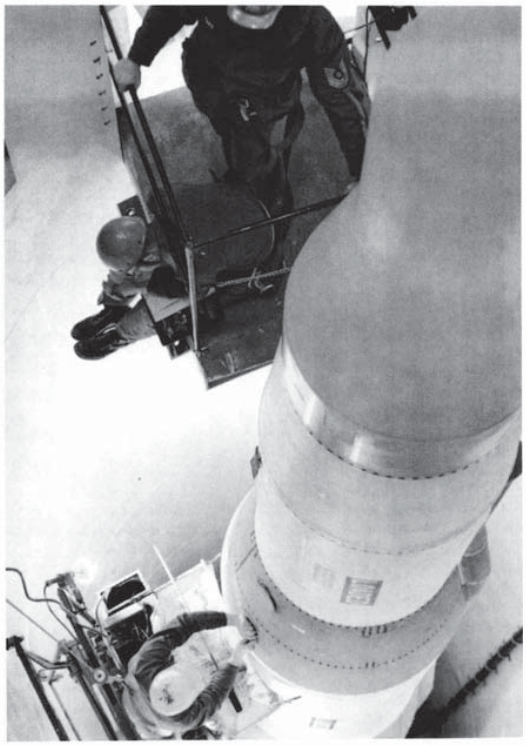

Missiles like this Minuteman II, shown in its North Dakota launcher, could have targeted Russian complexes.

The emergence of a Soviet missile defense system also spurred U.S. development of penetration aids ("penaids") and multiple independently targetable reentry vehicles (MIRVs), which vastly increased the U.S. stockpile. The United States undertook these efforts even though the Soviet ABM system was limited—similar in scale to the non-nuclear system planned by the Bush administration, which purports to defend against small attacks.

By reexamining the Soviet missile defense system of the late 1960s and how U.S. war planners might have planned to destroy it, and then by looking at how nuclear targeting is done today, it is clear that construction of a U.S. missile defense is actually cause for concern.

Soviet missile defense, 1968

The Soviet Union first deployed ballistic missile defense systems in the late 1960s. The most important was the A-35 anti-ballistic missile (ABM-1) defense system around Moscow, which began limited service in November 1967 with a few interceptors. The second, known as the Tallinn system, was located near Leningrad (now St. Petersburg) and became operational around the same time.

The A-35 Moscow system was originally designed to simultaneously intercept as many as eight incoming reentry vehicles. But there were doubts about whether it could intercept that many missiles, or missiles with multiple warheads and/or pen-aids (decoys that confuse radars). By 1968, the system was required to intercept only a single warhead or a single strike.

The initial system included 64 Galosh interceptors (ABM-1A, later upgraded to ABM-1B) located at four launch complexes outside Moscow. The Galosh had a 300-kilometer range and carried a warhead with a 2–3 megaton yield. Descriptions of the Soviet ABM system normally mention only four complexes, but a 1970 CIA report reveals that each complex consisted of two distinct launch sites separated by 4–7 kilometers. The four pairs of launch sites, the last of which became operational in early 1970, were arranged in a half-circle facing northwest, 85 miles (136 kilometers) from Moscow's center. Each launch site had eight reloadable aboveground launchers and three Try Add radars—one large radar for tracking and two smaller ones for tracking and guidance. A large Dog House tracking radar was built about 68 miles (109 kilometers) southwest of Moscow to track incoming reentry vehicles and provide battle management.

In addition to revealing the interceptor launch complexes, a CIA map released under FOIA shows that Moscow was also surrounded by 48 launch sites equipped with SA-1 Guild surface-to-air missiles. Twenty-six of the sites circled Moscow about 50 miles (80 kilometers) from its center; the other 22 sites formed an inner ring about 30 miles (48 kilometers) from Moscow's center. The 12-meter-long Guild missile had a range of 50 kilometers and could carry either a conventional or nuclear warhead.

Successful interception of reentry vehicles requires advance warning. In 1964, construction began on Hen House early warning radars, one at Skrunda in Lithuania and another at Olenegorsk on the Kola Peninsula. Hen House radars were designed to assess the size of an attack, confirm warnings from satellites and over-the-horizon radars, and provide target-tracking data to support ABM interceptor launches. The radars, located in the corridors through which U.S. ICBMs would strike Moscow, were almost entirely undefended and extremely vulnerable to the blackout that would result from nuclear airbursts.

The Tallinn system, named for the location where it was first detected, was deployed in a barrier line across the northwestern parts of European Russia, around Leningrad, and some parts of the southern approaches. After the conventionally armed SA-5 Griffon system was terminated in 1963, deployment of nuclear-capable SA-5B Gammon interceptors began at the old sites, with new sites constructed at Cherepovets, Liepaja, and Tallinn. The upgraded system became operational around 1966 or 1967.

In 1968, the total Tallinn system consisted of nearly 30 operational launch complexes with a similar number under construction. Each complex generally consisted of three launch sites. Each site had six SA-5B Gammon launchers and a

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modest-sized Square Pair radar. Of the 30 operational complexes, only six were close enough to the Hen House radars in Olenegorsk and Skrunda to have a potential ABM role (see "Soviet ABM System, 1968," p. 73).

There was considerable disagreement within the U.S. intelligence community at the time about whether the improved Tallinn system was to defend against aircraft, ballistic missiles, or some combination of the two. The Defense Intelligence Agency (DIA) agreed with the air force, which in late 1967 concluded that the system "possesses significant capabilities in both a terminal defense and area ABM role." But six months later, in a memorandum for President Lyndon Johnson, newly appointed Defense Secretary Clark Clifford said an ABM capability "now appears unlikely."

The CIA concluded that it did "not believe there is any deployment of ABM defenses outside the Moscow area," and the Tallinn system was "unlikely to have a present ABM capability," though it acknowledged, "the state of available evidence does not permit us to exclude this possibility." This view was shared by the navy, which decided that the system had "negligible capabilities against ballistic missiles."

There was general agreement that the limited Moscow and Tallinn systems would not be able to counter a large U.S. ballistic missile attack. In fact, the CIA later concluded that it "doubt[ed] that the Soviets will have an ABM system worth deploying against the U.S. threat in the foreseeable future."

The effect on U.S. nuclear planning

Despite disagreements and doubts, U.S. nuclear planners gave high priority to targeting the Moscow and Tallinn systems, worrying that even a limited ABM capability could diminish a strike against Soviet ICBM silos by U.S. ICBMs, which would overfly Moscow.

Soviet planners estimated in the early 1970s that Moscow would be targeted by at least 60 warheads of 1 megaton each. Newly declassified U.S. documents show that they were fairly accurate. A strike plan against the Moscow and Tallinn defenses, to ensure "penetration of the ICBM force," was incorporated into the single integrated operational plan (SIOP) war plan and entered into effect January 1, 1968. In addition to an undisclosed number of Polaris submarine-launched ballistic missiles (SLBMs), the plan involved "more than 100 Minuteman" ICBMs—about 10 percent of the U.S. ICBM force at the time. The attack would come in two closely coordinated waves. In the first salvo, Minuteman I/II and Polaris missiles would strike the Hen House early warning radars and their Tallinn system defenses. In the second wave, the Dog House radar and the Try Add system around Moscow would be attacked.

Assumptions about the 1968 attack

In attempting to reconstruct how U.S. nuclear war targeters might have devised such a strike plan we have made some assumptions about the targets and the weapons. The CIA's 1967 National Intelligence Estimate concluded that Moscow's ABM system did not "cover all of the multidirectional U.S. missile threats to Moscow; it is subject to saturation and exhaustion," and "none of the system components are hardened against nuclear bursts."

The strike plan would likely have exploited these weaknesses to the fullest and made use of the surprise effect of the significantly shorter flight time of SLBMs. So we have assumed that the Polaris missiles were targeted against the soft Hen House and Dog

Projected U.S. ABM suppression strike, 1968*

Target	Weapon**		Warhead		Total	
	Type	No.	Type	Yield (kt)	Warheads	Yield (kt)
Moscow system						
Dog House radar	Polaris A3	2	W58	200	6	1,200
Eight ABM launch complexes	Minuteman I/II	64	W56	1,000	64	64,000
Subtotal		*66*			*70*	*65,200*
Tallinn system						
Tallinn launch complex	Minuteman I/II	8	W56	1,000	8	8,000
Liepaja launch complex	Minuteman I/II	8	W56	1,000	8	8,000
Cherepovets launch complex	Minuteman I/II	8	W56	1,000	8	8,000
Three Leningrad complexes	Minuteman I/II	24	W56	1,000	24	24,000
Subtotal		*48*			*48*	*48,000*
Early warning radars* **						
Hen House (Skrunda)	Polaris A3	2	W58	200	6	1,200
Hen House (Olenegorsk)	Polaris A3	2	W58	200	6	1,200
Subtotal		*4*			*12*	*2,400*
Total		**118**			**130**	**115,600**

kt=kilotons. *Based on 100+ Minuteman I/II missiles, plus Polaris missiles, designated for 1968 Soviet ABM suppression. (U.S. Strategic Air Command, "History of U.S. Strategic Air Command January–June 1968," February 1969, p. 300. Partially declassified and released under FOIA.) **The assignment of individual weapons to individual targets is not known. We assume each launch complex was targeted by eight Minuteman missiles, each carrying one W56 warhead (1-megaton yield). ***Two other Hen House radars were located near China but could not detect missiles launched over the North Pole.

Characteristics of U.S. nuclear weapons

	Weapon	Yield (kilotons)	Accuracy (meters)*	Reliability**	MIRVs
1968					
	W56 (Minuteman I/II)	1,200	930	80 percent	1
	W58 (Polaris A3)	200	1,480	80 percent	3
1989					
	W78 (Minuteman III)	335	300	80 percent	2–3
	W76 (Trident I C4)	100	460	80 percent	8

MIRVs=multiple independently targetable reentry vehicles. *Circular error probable.
**Average reliability.

House radars, while Minuteman ICBMs were focused on the interceptor complexes. Moreover, since we don't know the capability the nuclear war planners assigned SA-5B and ABM-1B interceptors, or whether they considered these longer-range Moscow interceptors more capable (they probably were), we have assigned an equal number of attacking warheads per launch site.

Based on these assumptions and detailed calculations described below, the use of "more than 100 Minuteman" ICBMs and at least six Polaris SLBMs against the Soviet missile defense system's 17 individual facilities results in a staggering average of eight 1-megaton warheads per interceptor launch site around Moscow and Leningrad. The combined force of the strike exceeds 115 megatons—the equivalent of more than 7,500 Hiroshima bombs. Under these assumptions, the Moscow system would be clobbered with 70 warheads; the Tallinn system would be hit with 48 (see "Projected U.S. ABM Suppression Strike, 1968," p. 71).

Modeling the 1968 strike

To better understand the methodology by which U.S. nuclear war planners probably arrived at such an enormous strike plan, we performed calculations of target hardness, damage expectancies, and nuclear weapons effects. Our assumptions about the characteristics of the two types of attacking U.S. nuclear weapons are provided (see "Characteristics of U.S. Nuclear Weapons," above). It is important to note that at the time, high yields were used to compensate for the weapons' relative inaccuracy. A 1-megaton warhead can destroy residential structures out to a radius of about 4.5 kilometers from its ground zero. Many currently deployed U.S. nuclear weapons can do more damage at lower yields because of significantly higher accuracies.

This strike has two types of targets: ABM radars, and surface-launched ABM interceptor missiles. The targets' hardness and the characteristics of the attacking weapons would dictate to 1968's U.S. nuclear war planners how many nuclear weapons to assign each target, and, for each weapon, the height of burst (HOB).

The height of burst determines whether there is fallout from a nuclear explosion; above a certain height, no fallout would be expected because the detonation is too high to kick up ground debris. For the attacking weapons in this scenario, the "no-fallout HOB" is 935 meters for a 1.2-megaton weapon and 457 meters for a 200-kiloton weapon. To increase damage to a hardened target, war planners may call for a HOB lower than the no-fallout height. The "optimum HOB" maximizes the area exposed to a given blast pressure. For some targets and nuclear yields, the optimum HOB is above the no-fallout height (as at Hiroshima and Nagasaki, for example).

A high-yield nuclear weapon detonated at a lower height could produce hazardous radiation levels hundreds of miles from ground zero. With information from the partially declassified 1989 NATO Target Data Inventory (NTDI) Handbook, we calculated the hardness of the Soviet ABM targets and the optimum heights of burst for the attacking weapons. The optimum heights of burst are above the no-fallout HOB for both target types; this would avoid radiation contamination of Russia and Europe. Factoring in weapon accuracy and reliability, we can also compute the kill probability for an individual warhead on a specific target (see "Optimized U.S. Nuclear Forces Attack on Soviet ABM Targets," p. 74).

Our calculations show that, using this methodology, a couple of W56 Minuteman warheads were needed to destroy each ABM launch site. The fact that the U.S. nuclear war planners of 1968 assigned about eight warheads to each target implies that they were concerned with the effectiveness of the Soviet missile defenses and used extra warheads to overwhelm them. The six Polaris warheads assigned to each radar target would have achieved a combined 88 percent kill probability.

Substantial blast and fire damage would be expected from the strike. Central Moscow would be initially undamaged but surrounded by a semi-circle of fire soon after the attack. If rain or snow were falling, radioactive contamination of Moscow might occur because of the phenomenon of rainout.

Pen-aids and MIRVs

Our reconstruction of the ABM strike does not take into account how well the Soviet missile defense systems would have worked. What our calculations do show, however, is that U.S. planners added a large number of weapons to the strike plan to overcome any attrition by the system.

In the early to mid-1960s, in anticipation of the Soviet missile defense

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system, the United States developed pen-aids (decoys and chaff) to confuse interceptors. The United States wanted all its missile systems, whether SLBMs or ICBMs, "to be equipped with decoys capable of penetrating both area and local ballistic missile defenses." Some U.S. ICBMs had pen-aids, others did not; the Polaris SLBMs did not carry decoys (although subsequent Poseidon and Trident weapon systems did). In the 1968 strike plan described above, the Minuteman I reentry vehicles were equipped with "retro-rockets," and the Minuteman II carried Mk-11C reentry vehicles and Mk-1 pen-aids when available.

Another fundamental U.S. countermeasure to "saturate" the Soviet ABM system was the development and deployment of MIRVs. Many declassified documents from the time describe the MIRV development effort in an ABM context. The Polaris A3 carried three reentry vehicles, but the Poseidon SLBM that began replacing it in 1971 carried an average of 10 MIRVed warheads. Each warhead had a yield of approximately 50 kilotons and more than three times the accuracy of the Polaris A3. This meant the Poseidon could "be used to saturate an ABM defense or to attack independent soft targets."

The Minuteman III, deployed in 1970, and the current Peacekeeper ICBM carry two or three and 10 MIRVs, respectively. Individual missiles were eventually configured with different mixes of reentry vehicles and pen-aids to meet specific requirements of the mission.

British nuclear targeting of ABM systems

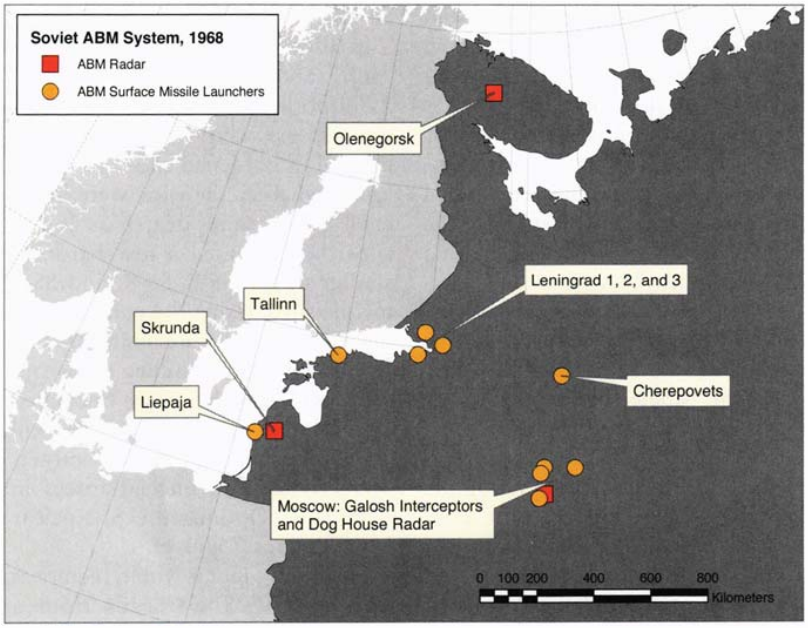
A British war plan supplemented the U.S. one. The first British nuclear-powered ballistic missile submarine (SSBN), the *Resolution*, sailed its first patrol in June 1968 armed with 16 U.S.-supplied Polaris missiles, each carrying three 200-kiloton warheads. Three more subs followed in June 1969, August 1969, and September 1970. The Polaris force took over the strategic role of the V-bomber.

By the end of the 1960s, targeting may have focused on Moscow, with all the missiles of a nuclear submarine committed to destroying the ABM system and the city. The capability of the Moscow ABM system might have limited the flexibility of British targeting by tying down most of the deployed force. Polaris appears to have been judged much more effective against the SA-5B Gammon interceptors of the Tallinn system. A 1970 study published by the British Atomic Energy Authority concluded that SA-5B interceptors were not a threat to British Polaris missiles, and that it would take only two Polaris missile payloads to saturate a standard SA-5B battery.

In 1972, the British government decided to develop a new front end for the Polaris missiles "designed specifically to penetrate [the] anti-ballistic missile defenses" around Moscow. This improved system, called Chevaline, was deployed in 1982. It carried pen-aids and three 40-kiloton maneuverable reentry vehicles that were "hardened" against the radiation effects of the nuclear ABM interceptors.

The Chevaline tied British targeting to Moscow. That changed in 1998, when Britain deployed Trident D5 missiles on four Vanguard-class SSBNs, returning flexibility to the war planners. "It is more than just the destruction of Moscow," said Field Marshall Nigel Bagnall, British chief of general staff from 1985 to 1988, "it is the destruction of the command and control system."

From late 1970 (when the British SSBN force became operational) through 1996 (when the Chevaline's operational deployment ended), the combined number of U.S. and British weapons assigned to suppress the Soviet ABM system may have been well over 200 warheads.



The Soviet ABM upgrade

Aware of the severe limitations of its A-35 Moscow ABM system, the Soviet Union began upgrading it in the mid-1970s. Like its predecessor, the upgraded system, called A-135, was designed merely to provide an "adequate" defense (as opposed to an "optimum" defense) against threats like a renegade U.S. SLBM attack, a "limited, provocative" U.S. ICBM at-

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Optimized U.S. nuclear forces attack on Soviet ABM targets*

Attacking warhead	Target type	Optimum HOB**	Kill probability (excluding reliability)	Kill probability (including reliability)
1968				
W56; 1,200 kilotons	SA-5B/ABM-1B surface-to-air missiles	2,000 m	99 percent	79 percent
W58; 200 kilotons	Radar installations	900 m	38 percent	30 percent
1989				
W78; 335 kilotons	Hardened silos similar to those of SS-7/8/9s	0–225 m	74 percent	59 percent
W76; 200 kilotons	Radar installations	700 m	92 percent	74 percent

m=meters. *Not considering ABM system effectiveness. **HOB=height of burst

tack, or a Chinese attack with as many as 100 intermediate-range missiles. The Moscow ABM capability was diminished by the reduction of interceptors in 1979–1980 from 64 to 32.

The upgrade was formally completed in 1989 (but had significant problems and was not fully operational until 1995). It added 68 launchers for a total of 100, the maximum permitted under the Anti-Ballistic Missile Treaty. Four new launch sites were built closer to Moscow, with new Gazelle (ABM-3) interceptors (17 launchers each) based in hardened silos to strike reentry vehicles inside the atmosphere. The Gazelle has a range of 80 kilometers and carries a 10-kiloton warhead.

The improved surface-mounted Galosh (ABM-1B) interceptors, of which only 16 of the original 64 remained in 1987, were replaced with 32 long-range Gorgon (SH-11/ABM-4) interceptors, deployed in hardened silos to engage incoming reentry vehicles outside the atmosphere. In 1989, there were four Gorgon sites with eight silos each. The Gorgon has a range of about 350 kilometers and carries a 1-megaton warhead.

The A-135, which some claimed was a scaled-up version of the U.S. Nike-X system, included a new Pillbox phased-array radar with 360-degree coverage at Pushkino, northeast of Moscow. The Pillbox, which became fully operational in 1990, was connected to other radars to track incoming warheads and guide the interceptor missiles toward their targets. The Soviets upgraded the Hen House radar at Skrunda to a much more capable large phased-array radar (LPAR), and added another LPAR to the system at Pechora in the northeastern Urals.

A U.S. response to the Soviet upgrade

Given the Soviet ABM modernization, how might U.S. nuclear planners have targeted the new A-135 system in 1989? Unlike our 1968 case study, neither the number of weapons nor their characteristics have been declassified. But from what we know about 1968 planning, targeting methodology, and our calculations of the above strike, it is possible to make a reasonable guess.

Well before the A-135 was completed, the United States concluded that despite the improvements, "the system cannot presently cope with a massive attack."

"With only 100 interceptor missiles," the Pentagon explained, "the system can be saturated, and with only the single Pillbox radar at Pushkino providing support to these missiles, the system is highly vulnerable to suppression." Even so, the Pentagon acknowledged, "It does provide a defense against a limited attack or accidental launch."

For the nuclear planners, one of the most important features of the upgraded Soviet system was that the new Gazelle interceptors could engage ICBM and SLBM reentry vehicles *after* most pen-aids were lost during reentry through the atmosphere. This capability meant that more attacking warheads would be needed to defeat the ABM system.

To better calculate and predict the loss of warheads in an attack, U.S. nuclear planners in 1986 acquired a new tool—the multiple engagement model (MEM). Developed by the Joint Strategic Target Planning Staff in charge of the SIOP, the MEM simulates warhead attrition caused by ABM interceptors.

Because of their capability for surprise, we assume that SLBMs in 1989 were primarily used to target the radars, much like the 1968 plan. Unlike in 1968, however, the new Poseidon and Trident I C4 SLBMs were equipped with pen-aids. Moreover, we assume that individual SLBMs assigned to take out the radars had been downloaded to carry only a few warheads (see "Characteristics of U.S. Nuclear Weapons," p. 72).

In 1968, Soviet interceptors were "soft" aboveground targets, but in 1989 both the Gorgon and Gazelle interceptors were deployed underground in hardened silos. We don't know whether the silos were hardened to the same degree as ICBM silos, but assumed a low hardness similar to the SS-7, SS-8, and SS-9 missile silos. Using the vulnerability numbers from the declassified NTDI Handbook, and including the weapon system's reliability, we calculated the optimum height of burst and kill probabilities for Soviet ABM targets attacked by U.S. nuclear forces in 1989 (see "Optimized U.S. Nuclear Forces Attack," above).

This shows that it would require at least two W78 warheads from a

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Minuteman III, detonated at 225 meters, to achieve a kill probability greater than 80 percent for each interceptor silo. For the softer radar installations, a single W76 warhead detonated at 700 meters would have a kill probability of 74 percent. We have therefore assumed that each silo would be targeted with one ICBM with at least two W78 warheads at surface or shallow burst (approximately 200 meters), and that each radar would be targeted with two airburst W76 warheads from an SLBM.

Because each Gorgon launch site included eight interceptor silos, and each Gazelle launch site had nine silos, to achieve a kill probability of more than 80 percent would require a staggering 16–18 warheads per launch site. As a result, we estimate that a 1989 strike against the Soviet ABM system would have required more than 100 ICBMs and SLBMs with more than 200 warheads, for a combined explosive power of 68 megatons (see "Projected U.S. ABM Suppression Strike, 1989," p. 77).

Radioactive fallout from airbursts over the radar facilities would be limited, but the use of many surface or near-surface bursts over the interceptor launch sites would create considerable fallout over Moscow and the surrounding areas. Calculations performed with a U.S. Defense Department computer program, using historical weather patterns for December, show that an unsheltered population in Moscow and outside the city to a distance of 35–75 miles would receive a lethal dose of up to 10,000 rem during the first 48 hours after the attack. The radioactive plume would be carried by prevailing winds for hundreds of miles (see "Fallout From Projected U.S. Attack, 1989," below).

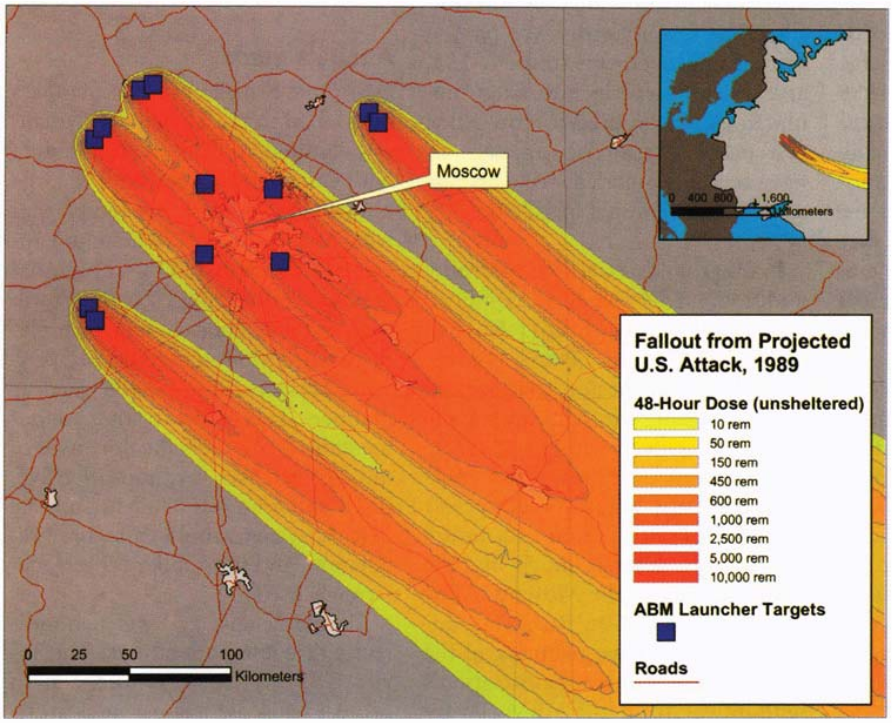
Modern anti-missile defense strike planning

Although U.S. offensive capabilities have changed considerably since 1989 with the advent of the Peacekeeper ICBM and Trident II D5 SLBM, the basic ABM mission remains the same: to destroy the ABM system and then the Russian leadership targets in Moscow, and to ensure penetration of the main ICBM force against Russian silos to the south and east.

In the late 1990s, the effects of the Soviet Union's demise reduced Russian ABM capabilities. The Skrunda radar closed in 1998, leaving a significant gap in Russia's ability to detect submarine missiles launched in shallow trajectories.

The same year, signs began to emerge that the Soviet ABM system was undergoing a more fundamental change—replacement of some or all of the nuclear warheads with *conventional* warheads. In February 1998, the commander in chief of the Strategic Rocket Forces said that the system needed some minor modifications, but that the "nuclear umbrella" over Moscow would once again be opened. A few days later, Col. Gen. Vladimir Yakovlev, commander in chief of strategic missile forces, suddenly declared that the ABM system, with conventional warheads on the Gorgon and Gazelle interceptors, was combat-ready and would be placed on 24-hour alert status.

Shortly thereafter, Gen. Eugene Habiger, U.S. commander of Stratcom, bluntly told reporters: "I'm at odds with the intelligence community regarding the ABM system around Moscow, in terms of its capability. . . . My view is the system is not as capable as the intelligence community says." Habiger added, "The Russians have told me that the system is no longer operational." Two months later, retired Russian generals told a conference in Washington, D.C., that Russia had removed the nuclear warheads from its ABM interceptors and replaced them with conventional warheads.



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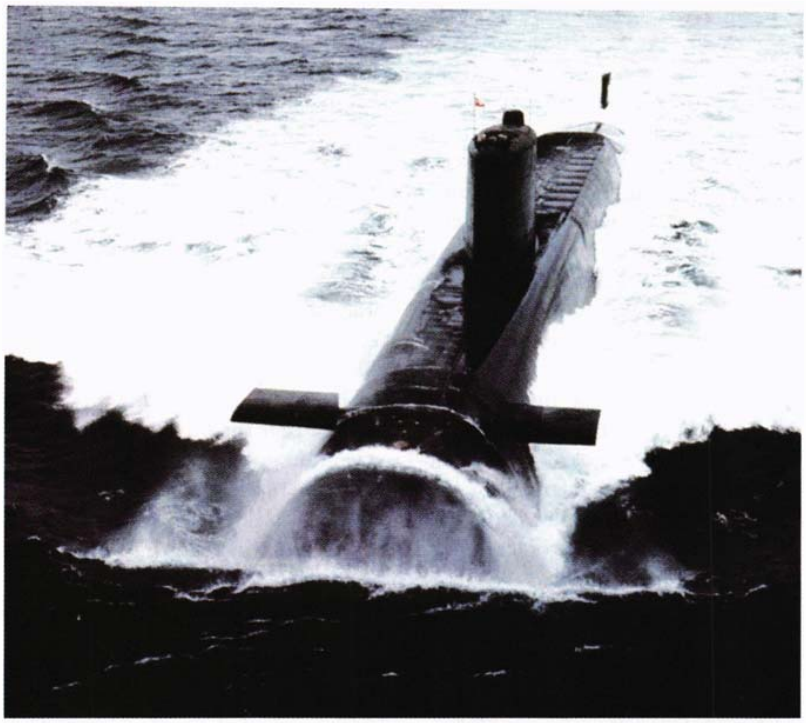

Britain's *Resolution* was armed with nuclear-capable Polaris missiles.

ROYAL NAVY

Armada International echoed this in April 2002, reporting that the A-135 system was stood down briefly in 1997–1998 for that purpose.

In contrast with these reports, British Defence Minister George Robertson wrote in late January 1989 to a member of Parliament about the status of the Russian ABM system: "We assess that the Moscow anti-ballistic missile system comprising the short range Gazelle and longer range Gorgon interceptors remains operational and effective. . . . Deployment of any significant upgrades in the near future appears unlikely."

Whether or not the system is still nuclear armed, it appears operational. In November 1999, Russia launched an unarmed Gazelle interceptor from the Moscow system in the first test launch since 1993. The U.S. State Department said the test was "distressing," and that "Russia is raising the specter of an arms competition when what we're trying to do is work cooperatively with them to focus on rogue states."

A second test followed in October 2002, when a long-range Gorgon interceptor was launched from the Sary Shagan test range in Kazakhstan. The test allegedly was part of further improvements to the A-135, and was followed by a Russian simulated attack on the Moscow ABM system. The exercise appears to have been a simulated strike against a future U.S. limited missile defense system.

In 2003, Russia decided to deploy additional SS-19 ICBMs equipped with MIRVed warheads. Russian President Vladimir Putin boasted that "their combat potential, including penetrating through any missile defense systems, is without peers."

This seems to indicate that Moscow is already adjusting its nuclear planning in anticipation of a future U.S. missile defense, much like the U.S. response to the Moscow ABM system in the 1960s. Russia is conducting its strategic planning in the context of the Bush administration's withdrawal from the ABM Treaty and construction of a 100-interceptor missile defense.

And despite the newly declared partnership with Russia, U.S. nuclear planners appear to be refining their nuclear-strike planning against the Russian ABM system. In November 2003, Stratcom initiated a new round of upgrades to its ABM attack-simulation program.

Major U.S. early warning radars are deployed at Thule, Greenland, and Fylingdales, England. (Additional facilities are scheduled to be built in Japan.) If these sites are not already considered high-value targets as central components of a missile defense system, they soon would be—just like the Soviet ABM radars, which became priority targets for U.S. planners.

An upgrade to the Thule and Fylingdales radars is part of the Bush administration's missile defense effort. Whether these facilities might be targets has created some debate in both countries, but the British and Danish governments have both dismissed the risks and agreed to support the Bush plan.

A mug's game

U.S. (and British) nuclear planners responded to the Soviet deployment of a limited missile defense system with enormous firepower. The large number of nuclear weapons that were assigned to overwhelm the Soviet ABM system and the substantial technical efforts the U.S. undertook to defeat it provide chilling examples of the attention missile defense systems attract from hostile nuclear planners. It is a history that fundamentally contradicts the portrayal of missile defenses as non-offensive, threatening no one. Ballistic missile defense systems threaten secured retaliation, and for smaller powers, deterrence itself.

Missile defense systems also indirectly threaten populations. The Soviet ABM system was intended to protect Moscow against nuclear at-

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tacks, but rather than shielding the capital from nuclear peril, the system in fact had the opposite effect of attracting nuclear warheads. Many other facilities would have been targeted in addition to the ABM system, including political and military leadership targets. "We must have targeted Moscow with 400 weapons," a former Stratcom commander has stated.

What is the relevance of this today? One could argue that all of this occurred during the Cold War, that U.S.–Soviet/Russian strategic competition is over, and that smaller nuclear powers do not have enough nuclear weapons to overwhelm missile defense systems. That may or may not be so. But at the superpower level, the action-reaction momentum seems to continue.

The United States apparently still targets the Moscow ABM system, and Russia appears to have begun adjusting its own forces to a future U.S. missile defense. The Bush administration's claim that its system will not be of concern to Russia may be true in a hypothetical Russian first-strike scenario with hundreds of missiles. But Russian planners are likely to be much more concerned with the effect on their surviving retaliatory capability after a hypothetical U.S. first strike has reduced the number of operational missiles. This will almost certainly drive new modernization efforts, newfound U.S.-Russian partnership or not.

For China, the situation is drastically different. The credibility of its nuclear retaliatory deterrent will be fundamentally challenged by a U.S. missile defense system. Ironically, the situation is similar to that in the late 1960s, when China was the "rogue" state used as the justification to build the first limited U.S. missile defense system. Back then, a system with 100 interceptors, the same capacity planned by the Bush administration today, was thought to be capable of reducing U.S. fatalities from a Chinese attack to "possibly zero, if the number [of Chinese missiles] does not reach 25." China today has approximately 20 ICBMs capable of hitting the U.S. mainland.

The current Chinese modernization program began more than a decade ago. The U.S. intelligence community estimates that by 2015, China will increase "several fold" the number of warheads primarily targeted against the United States. The Bush administration's claim that China will continue to modernize whether or not the United States builds missile defenses is a dangerous gamble that ignores the magnitude of the impact on the Chinese deterrent. "That impact will lessen if, as expected, China increases strategic nuclear arms over the next decade," said Stratcom commander Adm. James Ellis in 2001. But the U.S. experience with targeting Soviet missile defenses suggests that even the 75–100 warheads the U.S. intelligence community predicts China will have by 2015 may not be enough for it. The United States needed well over 100 missiles with even more warheads, pen-aids, and SSBNs to overwhelm the 1968 Soviet ABM system. The Chinese reaction to a more capable U.S. missile defense may spark similar changes in China's capabilities, as the CIA predicts: "MIRVing and missile defense countermeasures would be factors in the ultimate size of the force."

In the longer run, a missile defense system could also cause a doctrinal change, prompting China to abandon its purely retaliatory posture and replace it with counterforce targeting similar to that of the United States and Russia. As Admiral Ellis explained, "the more effective a U.S. missile defense system is in diminishing [the] retaliatory capability of Russian and Chinese deterrent forces, the greater the incentive for expansion of these forces to maintain their perceived deterrent effect."

The dynamics of nuclear competition and the history of the U.S. targeting of the Soviet ABM system remind us that missile defense systems are potent drivers of offensive nuclear planning. The missile defense that the Bush administration is building will be no exception, despite its limited capability, and it will almost certainly attract nuclear targeting from the start. ✲

Projected U.S. ABM suppression strike, 1989

Target	Weapon*		Warhead		Total	
	Type	No.	Type	Yield (kt)	Warheads	Yield (kt)
Moscow system						
Cat House radar	Trident I C4	1	W76	100	2	200
Dog House radar	Trident I C4	1	W76	100	2	200
4 Gorgon launch complexes	Minuteman III	32	W78	335	64	21,440
4 Gazelle launch complexes	Minuteman III	68	W78	335	136	45,560
Subtotal		*102*			*204*	*67,400*
Early warning radars**						
Hen House radar (Olenegorsk)	Trident I C4	1	W76	100	2	200
LPAR radar (Skrunda)	Trident I C4	1	W76	100	2	200
LPAR radar (Baranovichi)	Trident I C4	1	W76	100	2	200
Subtotal		*3*			*6*	*600*
Total		**105**			**210**	**68,000**

kt=kilotons. *We assume each Gorgon launch complex was targeted by eight Minuteman III missiles, each carrying two 335-kiloton W78 warheads; that each Gazelle complex was targeted by nine Minuteman III missiles, also each carrying two W78s; and that each Trident was downloaded to at least two warheads. Both Moscow radars could also be targeted by warheads from a single missile. **The LPAR and Pillbox radars at Pechora and Moscow, respectively, were under construction in 1989, and would later be targeted as well.

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ATTACHMENT 16

April 2010

Still Poisoning the Well

Atrazine Continues to Contaminate Surface Water and Drinking Water in the United States

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The Earth's Best Defense

About NRDC

The Natural Resources Defense Council (NRDC) is a national nonprofit environmental organization with more than 1.3 million members and online activists. Since 1970, our lawyers, scientists, and other environmental specialists have worked to protect the world's natural resources, public health, and the environment. NRDC has offices in New York City, Washington, D.C., Los Angeles, San Francisco, Chicago, Montana, and Beijing. Visit us at www.nrdc.org.

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Executive Summary

Watersheds and drinking water systems across the nation remain at risk for contamination from the endocrine-disrupting pesticide atrazine. An herbicide linked to harm to wildlife and humans, atrazine is the most commonly detected pesticide in U.S. waters. Although banned in the European Union in 2004, atrazine is still one of the most widely used pesticides in the United States.

In our 2009 report, *Poisoning the Well*, NRDC obtained and analyzed results of surface water and drinking water monitoring data for atrazine and found pervasive contamination of watersheds and drinking water systems across the Midwest and Southern United States. This new report summarizes scientific information that has emerged since the publication of our initial report. Findings based upon updated monitoring data on the presence of atrazine in surface water and drinking water draw attention to the continuing problem of atrazine contamination and the insufficient efforts by the EPA to protect human health and the environment.

Pervasive Contamination of Watersheds and Drinking Water Continues

Watersheds

Our analysis of the atrazine monitoring data taken from twenty watersheds between 2007 and 2008 confirms that surfaces waters in the Midwestern United States continue to be pervasively contaminated with atrazine.

- All twenty watersheds showed detectable levels of atrazine, and sixteen had average concentrations above 1 part per billion (ppb)—the level that has been shown to harm plants and wildlife.
- Eighteen of the monitored watersheds were intermittently severely contaminated with at least one sample above 20 ppb. Nine had a peak concentration above 50 ppb, and three watersheds had peak maximum concentrations exceeding 100 ppb.
- The Big Blue River watershed in Nebraska had the highest maximum concentration of any watershed tested—147.65 ppb, detected in May 2008.

Drinking Water

NRDC also analyzed atrazine monitoring data taken between 2005 and 2008 from drinking water systems located all across the United States. Our analysis paints an equally disturbing picture about drinking water contamination.

- 80 percent of the raw water (untreated) and finished water (ready for consumption) samples taken in 153 drinking water systems contained atrazine.

Atrazine has been detected in watersheds and drinking water systems across the Midwest and Southern United States. View maps of atrazine contamination online at **www.nrdc.org/health/atrazine/**

- Of the 153 drinking water systems monitored,100 systems had peak maximum concentrations of atrazine in their raw water that exceeded 3 ppb. Two-thirds of these 100 systems also had peak maximum concentrations of atrazine that exceeded 3 ppb in the finished water.
- Six water systems had high enough atrazine levels to exceed the EPA drinking water standard of 3 ppb.

These results represent only a sampling of public water systems in the United States. Thousands more drinking water systems may be unknowingly contaminated with atrazine, since the federal government only requires monitoring four times a year—compared to the more frequent weekly and bi-weekly monitoring data that we analyzed here. As such, the full extent of atrazine contamination of watersheds and drinking water systems across the United States is unknown.

Harm from Atrazine Exposure is Well Documented

The dangers associated with atrazine use have been well documented, and scientific data continue to emerge that further bolster the health concerns associated with atrazine exposure. The pesticide is an endocrine disruptor, impairs the immune system, and is associated with birth defects. The adverse effects of exposure to atrazine are particularly harmful during critical periods of development. And in the presence of other pesticides, atrazine works synergistically to increase the toxic effects stemming from expose to the harmful chemicals.

Current Regulations Do Not Adequately Protect Human Health

Two statutes principally govern the regulation of atrazine. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA allows atrazine use both in agriculture (such as on corn, sorghum, and sugarcane) and at home (such as on lawns). Under the Safe Drinking Water Act, the EPA regulates the amount of atrazine that is allowed in drinking water. Specifically, only 3 ppb of atrazine (calculated based on a running annual average) is permitted in finished drinking water. NRDC believes a running annual average approach for drinking water is inadequate to protect human health, because even one-time exposures to developmental toxins like atrazine during critical periods of development may cause harm.

Our analysis of the data reinforces the fact that the monitoring schedule, set by the drinking water regulations, fails to guard against high spikes in atrazine levels or even ensure that the EPA's annual average limit on atrazine contamination is not being exceeded. Because public water systems are only required to take one to four samples per year, they are likely to miss a lot of the high spikes that we found. This means both that the EPA is ignoring high spikes of atrazine in drinking water and that the running annual average of atrazine in a system may actually be higher than suggested by four samples. Even short-duration exposures to atrazine should be regulated by the EPA.

Atrazine Use Imposes High Costs on Drinking Water Systems

Several studies have concluded that atrazine use provides only minimal benefits to crop production. On the other hand, the cost of treating drinking water for atrazine can add high costs to municipalities that have to install expensive treatment technology to remove the contaminant. Small systems located around agricultural areas where atrazine is frequently used may be particularly vulnerable to contamination problems and must spend a significant portion of their budgets to protect their customers from atrazine exposure. Water systems spend tens of thousands of dollars per year to maintain treatment systems that remove contaminants such as atrazine.

Recommendations for Reducing Atrazine Contamination

NRDC called for the phase-out of atrazine because of its harm to wildlife and potentially to people and because it has minimal or no benefits for crop production. Programs to improve water monitoring and encourage farmers to reduce their atrazine use are important next steps for addressing the problem of atrazine contamination while the EPA helps farmers transition away from the use of this pesticide altogether. NRDC recommends the following steps be taken to reduce atrazine contamination in U.S. waters

and minimize its impacts on human health and the environment:

1. The United States should phase out the use of atrazine.
NRDC strongly recommends that atrazine be phased out of all uses in the United States, including home gardens and golf courses. Evidence of atrazine's toxic effects on sensitive wildlife species and its potential risk to human health is abundant. The monitoring data show that high contamination levels in the Midwestern and Southern United States are pervasive. There is little compelling evidence that atrazine is needed by farmers.

2. Farmers should take immediate interim steps to reduce their atrazine use.
Farmers should take immediate steps to reduce their use of atrazine, including increasing reliance on a variety of non-chemical techniques for weed control. These include crop rotation, the use of winter cover crops, alternating rows of different crops, and mechanical weed control methods. Additionally, timing fertilizer applications to coincide with periods of greatest nutrient uptake by crops can avoid unnecessary fertilizer use that would fuel weed growth.

3. The EPA should monitor all vulnerable watersheds and require all future monitoring plans to identify worst case scenarios.
The EPA should broaden the monitoring program to assess all watersheds identified as vulnerable. The monitoring data in this update represent less than 2 percent of all the watersheds that are at highest risk from atrazine contamination. Future monitoring plans should be designed to identify the worst case scenarios occurring in vulnerable watersheds and in public water systems. More frequent sampling and sampling after big rainstorms and after fields have been treated with atrazine is necessary to assess the impacts of atrazine use on waterways. Such monitoring would provide a much more realistic view of the actual severity of the atrazine problem.

4. The EPA should publish monitoring results for each watershed and public water system sampled.
Monitoring results on the watersheds and the public water systems that were sampled under the two different monitoring programs were first made available to NRDC through Freedom of Information Act (FOIA) requests and litigation. People who live downstream of atrazine-treated fields have a right to know about high levels of atrazine contamination in their watersheds or drinking water systems. A publicly available website posting sampling data as it is analyzed and that regularly reports spikes of atrazine contamination would be an important step in the right direction, providing accessible information to the public. An interactive map of the data used in *Poisoning the Well* on NRDC's website allows users to see both watershed and drinking water data closest to their homes in graphical form.[1] This format is an example of what the EPA could do.

5. The public should use home water filtration systems and demand transparency of information from their water utilities.
NRDC recommends that consumers concerned about atrazine contamination in their water use a simple and economical household water filter, such as one that fits on the tap. Consumers should make sure that the filter they choose is certified by NSF International to meet American National Standards Institute (ANSI) Standard 53 for atrazine. A list of NSF/ANSI53-certified drinking water filters is available at www.nsf.org/certified/dwtu.

CHAPTER 1

A Fresh Look at the Harmful Effects of Atrazine

In our original 2009 report, *Poisoning the Well: How the EPA is Ignoring Atrazine Contamination in Surface and Drinking Water in the Central United States,* NRDC described the well-documented problems caused by exposure to atrazine, including hormone-disruption and immune system impairment in animals, and potentially in humans. Additional studies have since been published that further strengthen our conclusion that atrazine is harmful to wildlife and should not be in our waterways or drinking water. In this update, NRDC reviews new scientific studies that provide further evidence of the harmful effects of atrazine exposure to people and wildlife.

Atrazine Harms the Hormone System

At least four scientific studies published in late 2009 offer significant new laboratory evidence that atrazine interferes with normal hormone function, including reduced sperm production, reduced steroid production, and insulin resistance. One study reported an increase in male steroid hormones associated with a single-dose of atrazine in male rats.[1] In another study, male rats that ate atrazine-laced feed had significantly less sperm than rats not fed atrazine, even after only one or two weeks of eating the contaminated feed.[2] Importantly, the damaging effect on sperm production was dose-dependent; the more atrazine the rats ate, the lower their sperm count. While a dose-response relationship does not prove the existence of a causal relationship, its presence increases the scientific confidence that the outcome (in this case, hormone effects) is caused by the treatment (atrazine).

A third study documented a dose-dependent decrease in male hormone levels in the testicles of rats that ate atrazine-contaminated feed.[3] A fourth study reported effects of atrazine on a different hormone system leading to insulin-resistance and obesity after lab rats drank atrazine-laced water daily for five months.[4]

Adding to these findings, in early 2010, well-known frog expert Dr. Tyrone Hayes published a startling study. He reported that 10 percent of male frogs that were born and raised in water contaminated with only 2.5 ppb atrazine (less than the federal allowable standard for drinking water of 3 ppb) grew up with female sex characteristics, including reduced levels of male testosterone, reduced sperm levels, and eggs in their testes.[5] Even more disturbing, these atrazine-feminized males showed female mating behavior, attracted normal males, mated with them, and

produced viable larvae that grew into male frogs. Although scientists employed by Syngenta (the manufacturer of atrazine) have strongly criticized the study,[6, 7] Hayes' findings are in general agreement with other reports in the scientific literature and cannot be discounted.

A 2010 article published by University of South Florida researchers analyzed the findings of more than 125 independently published research studies of atrazine effects on freshwater fish and amphibians.[8] Their meta-analysis found that many of the studies reported the same health outcomes, even though the studies were in several wildlife species and used different research methods.[9] In particular, atrazine affected the hormone systems of freshwater fish and amphibian species in most studies, including effects such as altered time of metamorphosis (delayed in some studies and accelerated in other studies), impaired sperm production, and abnormal gonadal development. The consistent finding of endocrine disruption effects of atrazine across diverse species and in different independent studies strengthens the conclusions of each experiment and increases the scientific confidence that the findings are generally true.

Atrazine Harms the Immune System

In addition to the hormone effects identified in the meta-analysis mentioned above, the review paper by Rohr and McCoy also reported that atrazine caused impaired immune function and increased infection rates in aquatic wildlife living in atrazine-contaminated water.[10]

Furthermore, atrazine has been shown to act synergistically with other chemicals to increase their toxic effects by impairing the immune system. In a 2009 study, when tiger salamander larvae were raised for two weeks in water containing atrazine (20 or 200 ppb) or the pesticide chlorpyrifos (2, 20, or 200 ppb), no increase in deaths was observed.[11] However, when the larvae were exposed to the combination of atrazine and chlorpyrifos together, there was a significant increase in larval deaths from increased viral infection and disease. This study suggests that the two chemicals acting together can harm immune function more than either one alone. This finding is significant both because it is common for several pesticides to be found in waterbodies together and because many pesticide products, including atrazine, are packaged and sold as pesticide mixtures.

Atrazine May Increase Risk of Poor Birth Outcomes

New evidence links atrazine to poor birth outcomes in people. A 2009 study found a significant correlation between prenatal atrazine exposure and reduced body weight at birth.[12] The authors reviewed the birth records of more than 24,000 babies born in Indiana and localized each birth to the particular community water system where the mother lived. Their analysis showed that the mothers with the highest concentrations of atrazine in their tap water (above 0.7 ppb) for the duration of the pregnancy had a higher risk of having a baby with a low birth weight than those mothers with lower exposures (below 0.3 ppb). Low birth weight is associated with increased risk of infant illness and some diseases, such as cardiovascular disease and diabetes.[13]

Another 2009 study analyzed more than 30 million births across the United States and reported an increased risk of birth defects associated with mothers who became pregnant between April and July, when pesticides in waterways are at their highest levels.[14] The authors reported that among the pesticides monitored in the waterways, the risk was most closely associated with atrazine contamination. While this study did not measure drinking water levels specifically, the fact that the risk is highest when conception is timed with peak pesticide contamination in rivers and streams raises red flags. In 2007, a study found a significant association between atrazine water contamination levels and birth defects in the gut wall of newborn babies in Indiana.[15] In fact, this study found that the rate of this particular birth defect is higher in Indiana than the rate across the country. Although there are many water contaminants other than pesticides, such as pharmaceutical waste, that are likely to cause reproductive harm in Indiana and elsewhere, these other contaminants would not necessarily be expected to show the seasonal peaks that are found with agricultural use of pesticides.

These studies suggest that, in people, atrazine exposure during pregnancy may contribute to a higher risk of adverse birth outcomes when considered along with genetic factors and other environmental contaminants.

Farmers and Workers May Be Exposed To Unsafe Levels

A recent study of Iowa farmers reported finding atrazine metabolites in the urine of farmers who had recently applied atrazine, proving that they had been dosed with the pesticide.[16] Previous scientific studies have linked atrazine urine levels in farm workers and rural men to reproductive effects such as low sperm count and reduced sperm motility.[17, 18, 19] Interestingly, the Iowa study reported that the amount of pesticide in the urine was related to the amount applied to the field. As such, significantly reducing the amount of atrazine applied (or phasing out its use altogether) would presumably provide an immediate positive effect for farmers by reducing the contamination of their bodies.

CHAPTER 2

Revisiting the Problem of Atrazine Contamination

In *Poisoning the Well* NRDC analyzed surface water data collected between 2004 and 2006 and drinking water data collected in 2003 and 2004 from watersheds and water systems across the Midwestern and Southern United States pursuant to a U.S. Environmental Protection Agency (EPA) mandate. Unfortunately, little has changed in the way atrazine is regulated and overdue changes in how the government monitors for atrazine contamination and attempts to protect public health have not yet occurred.

NRDC's Original Analysis Showed Contamination of Watersheds and Drinking Water

NRDC's original report found that the surface waters of the Midwestern and Southern United States suffer from pervasive contamination with atrazine.[1] In fact, all 40 watersheds tested showed detectable levels of atrazine, and 25 had average concentrations above 1 ppb, the concentration at which the primary production of aquatic non-vascular plants (such as algae) is reduced. We determined that the watersheds with the 10 highest peak concentrations of atrazine were in Indiana, Missouri, and Nebraska. We also noted that some watersheds had at least one sample of very high atrazine levels (ranging from 50 ppb to more than 200 ppb).

Our previous analysis of drinking water data also revealed high levels of atrazine contamination in the drinking water in some public water systems.[2] More than 90 percent of the samples taken in 139 water systems had measurable levels of atrazine in both 2003 and 2004. Fifty-four water systems had a one-time peak atrazine concentration above 3 ppb.

Poisoning the Well revealed that while water systems could claim to be in compliance with the 3 ppb annual average limit for atrazine in drinking water under the Safe Drinking Water Act when calculated using a running annual average, more frequent monitoring showed that some systems actually exceeded the federal standard. In fact, three of the systems analyzed had running annual averages that exceeded 3 ppb. The EPA only requires systems to take between one and four samples per year to determine whether they comply with the standard. As a result, high spikes of atrazine that last for a few weeks can easily be missed. Another problem with the EPA's reliance on a running annual average is that it allows high spikes of atrazine in spring or summer to be offset by low or zero detections in the fall and winter. This update to last year's report reconfirms the danger posed by the unabated and

widespread atrazine contamination of surface and drinking water in the United States and the EPA's continued reliance on running annual averages that are based upon too few samples each year.

Action Undertaken by the EPA Remains Inadequate

In its 2006 final re-registration decision for atrazine, the EPA acknowledged concerns about human exposure to atrazine. The EPA classified the chemical as a Restricted Use Pesticide because of its hazard to ground and surface water.[3] As a result, atrazine can only be applied by a pesticide professional; however, there is an exception for lawn care, turf, and conifer trees, allowing homeowners to apply it themselves. According to the EPA's own assessment, this exception may, nonetheless, lead to unsafe exposures that exceed its "level of concern" for homeowners who apply the products to their lawns.[4] The EPA also expressed concern that children who play on atrazine-treated lawns are also at risk for potentially unsafe exposures.[5]

The EPA found that workers, including farmers, who mix, load, and apply pesticides, like atrazine, also risk unsafe exposures. It found that exposures can result from accidental spills and splashes onto the skin or clothing, or inhalation of fumes and small droplets when the chemical is being applied to the field. It noted that exposure can even occur when those applying the chemicals follow all the label requirements for using protective clothing and equipment.[6]

The EPA also acknowledged concerns about the adverse effects that atrazine can have on wildlife. After washing from the field into streams and rivers with rainfall, atrazine kills algae and other beneficial aquatic plants that provide food, shelter, and oxygen for aquatic animals. The EPA has found, for example, that the effects of atrazine on aquatic ecosystems "may be severe due to the loss of up to 60 to 95 percent of the vegetative cover, which provides habitat to conceal young fish and aquatic invertebrates from predators."[7] The EPA assessment goes on to note that "numerous studies have described the ability of atrazine to inhibit photosynthesis, change community structure," and kill aquatic plants at concentrations between 20 and 500 ppm.[8]

The EPA's conclusions likely underestimate the true extent of the problem. As part of ongoing consultations under the federal Endangered Species Act, both the U.S. Fish and Wildlife Service and the National Marine Fisheries Service have concluded that atrazine concentrations below these levels are likely to have negative effects on aquatic plant communities, which have negative effects on threatened and endangered species.[9]

Moreover, the approved agricultural application rates for atrazine are likely to result in adverse effects to many endangered species. For example, the EPA determined that an application rate of 1.1 or 1.2 pounds of atrazine per acre on corn or sorghum fields is unsafe (that is, it exceeds the EPA's acute toxicity level of concern) for some endangered aquatic invertebrates, endangered aquatic vascular plants, and endangered small herbivore mammals.[10] Yet, the maximum legal application rate is four pounds of atrazine per acre for sugarcane, and two pounds per acre for corn and sorghum. Even if typical use rates for these crops were half of the maximum legal rate, they would still lead to unsafe exposures for many plants and aquatic animals.

CHAPTER 3

Atrazine Contamination Continues to be a Widespread Problem

Poisoning the Well was based on our analysis of data collected by the atrazine manufacturer Syngenta in selected watersheds under the Ecological Watershed Monitoring Program and from drinking water systems under the Atrazine Monitoring Program. The EPA had required Syngenta to collect these data rather than issue a rulemaking to reduce the use of atrazine. Findings in our 2009 report were based on watershed data collected between 2004 and 2006 and drinking water data collected between 2003 and 2004.[1]

For this update, we analyzed the Ecological Watershed Monitoring Program data collected by Syngenta between 2007 and 2008 from 20 watersheds in Illinois, Indiana, Missouri, Nebraska and Ohio. Data was collected from early spring through the summer or fall.[2] Watersheds were chosen for monitoring in these two years based on earlier monitoring results obtained from 2004 to 2006 that showed elevated levels of atrazine approaching or exceeding the EPA's level of concern.[3] Some additional watersheds were chosen within or near those watersheds with high atrazine levels.

We also analyzed the Atrazine Monitoring Program drinking water data collected from 2005 to 2008.[4] During this period, Syngenta collected more than 35,000 water samples taken from 153 public water systems in 12 states. The water systems are located in California (2), Florida (4), Illinois (30), Indiana (13), Iowa (9), Kansas (31), Kentucky (4), Louisiana (4), Missouri (20), North Carolina (3), Ohio (22) and Texas (11). Testing was concentrated in the Midwest, where atrazine use is most common. Both raw water (untreated) and finished water (water ready for human consumption) were tested.[5]

Our updated analysis shows continuing pervasive contamination—at levels of concern—of both watersheds and drinking water that remains consistent with our original findings.

Watersheds Are Still Pervasively Contaminated with Atrazine

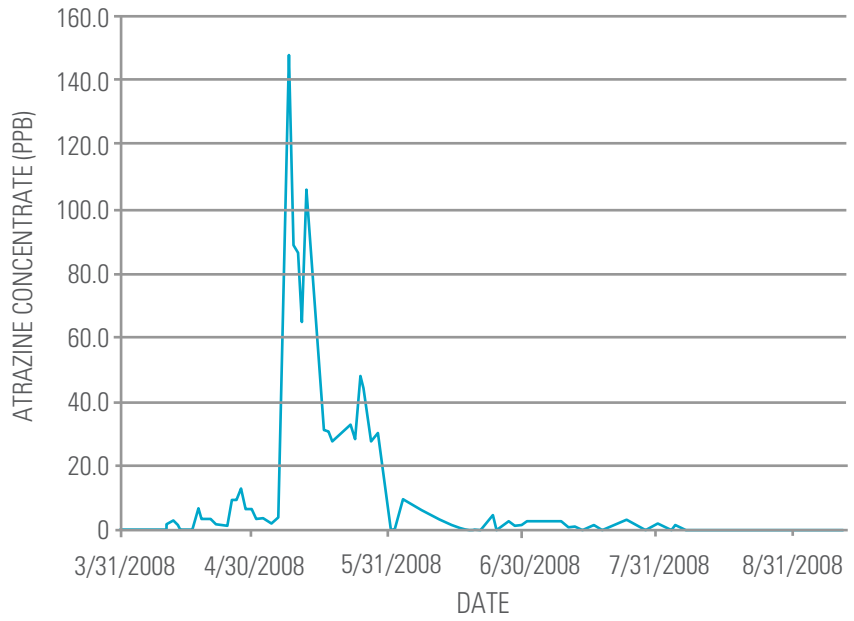
Many of the watersheds monitored showed high atrazine spikes well in excess of levels that are harmful to plants and wildlife. High atrazine concentration spikes were found to be widespread: 18 watersheds

had atrazine spikes above 20 ppb, and nine had spikes of 50 ppb or more (see Table 1 for the monitoring results from all twenty watersheds). The Big Blue River watershed (in upper Gage County, Nebraska) showed the highest maximum peak concentration of atrazine with 147.65 ppb in May 2008. More alarmingly, this high peak concentration lasted twelve days during which atrazine concentrations ranged from 27.92 ppb to 147.65 ppb (see Figure 1).

Table 1: Atrazine concentrations in all 20 monitored watersheds, 2007 – 2008

Watershed	Sampling Year	Number of samples	Atrazine Concentration (ppb)	
			Max.	Annual Avg.
Spring Creek, IL	2007	124	3.25 (6/2/07)	0.36
Iroquois River, IL	2007	139	12.69 (4/26/07)	0.84
Horse Creek, IL	2007	105	42.77 (5/16/2007)	2.41
Vermilion River, North Fork, IN	2007	101	12.15 (4/25/2007)	0.43
Little Pigeon Creek, IN	2007	88	2.95 (8/4/2007)	0.33
	2008	174	27.12 (5/3/2008)	1.10
Little Pigeon Creek, subwatershed, IN	2007	61	1.44 (4/27/2007)	0.30
	2008	155	15.10 (5/3/2008)	1.11
South Fabius River, MO	2007	102	91.60 (6/2/2007)	5.02
	2008	47	62.75 (6/3/2008)	2.03
South Fabius River, MO upstream	2008	192	78.20 (6/3/2008)	1.98
Youngs Creek, MO	2007	120	16.18 (4/26/2007)	2.33
	2008	225	56.60 (5/26/2008)	2.73
Seebers Branch, South Fabius River, MO	2007	124	65.73 (4/26/2007)	2.05
	2008	220	144.69 (5/12/2008)	4.20
Main South Fabius River, MO	2007	121	42.97 (5/4/2007)	2.00
	2008	219	33.60 (6/3/2008)	1.43
Long Branch, MO	2007	126	21.08 (4/26/2007)	3.18
	2008	225	37.83 (6/9/2008)	2.02
Long Branch, MO, main	2008	207	36.23 (5/25/2008)	2.80
Big Blue River, Upper Gage, NE	2008	173	147.65 (5/8/2008)	9.12
Big Blue River, Upper Gage, NE; adjacent site	2008	184	116.03 (5/7/2008)	8.45
Muddy Creek, NE	2008	175	67.81 (5/30/2008)	2.49
Big Blue River, Lower Gage, NE	2008	200	82.80 (5/22/2008)	2.07
Big Blue River, Lower Gage, NE; adjacent site	2008	188	32.90 (5/24/2008)	2.32
Lower Muddy Creek, NE	2008	153	50.00 (5/30/2008)	2.25
Licking River, North Fork, OH	2007	128	9.90 (5/16/2007)	0.62

Figure 1. Atrazine concentrations in the Big Blue River watershed (upper Gage County, Nebraska), March – August 2008



However, the Big Blue River was not alone; other watersheds had lengthy spikes as well. The Seeber Branch of the South Fabius River in Missouri had a 13-day spike with concentrations ranging from 5 ppb to 144.69 ppb between May 11 and May 23, 2008. Youngs Creek, also in Missouri, had an 8-day spike in May 2008 with concentrations ranging from 9.85 ppb to 56.60 ppb.

Some atrazine was detected in the sampled streams in all watersheds, with annual average atrazine concentrations ranging from 0.3 ppb in a sub-watershed of Little Pigeon Creek in Indiana to 9.12 ppb in the Big Blue River watershed in upper Gage County, Nebraska. Sixteen of the 20 watersheds had annual average concentrations above 1 ppb, the level at which primary production in aquatic non-vascular plants is reduced and which is likely to cause adverse effects on the ecosystems in and around these streams.[6]

Atrazine Contamination of Drinking Water Continues to be a Problem

Our analysis of the updated drinking water data from the Atrazine Monitoring Program again showed that a surprising amount of drinking water is contaminated with atrazine. Based on more than 35,000 samples, we found that atrazine was detected in 80 percent of the samples.

For samples of raw water, 100 water systems had maximum peak concentrations of atrazine above 3 ppb. For samples of finished water, 67 water systems had concentrations of atrazine above 3 ppb. In Piqua City Public Water System in Ohio, there was a maximum peak concentration of atrazine in the raw water of 84.80 ppb and in the finished water of 59.57 ppb. While another Ohio system, Mt. Orab Village Public Water System, had a higher raw water reading, Piqua had by far the highest maximum peak concentration of atrazine in finished water.

More startling, six systems had atrazine concentrations that exceeded the EPA drinking water standard, which is based on a running annual average:

Wayaconda, Missouri; Piqua City Public Water System, Ohio; Versailles Water Works, Indiana; Evansville, Illinois; Blanchester Village, Ohio; and Beloit Water Department, Kansas..[7] Of those six systems, two had also exceeded the drinking water standard in 2003 - 2004 (Versailles Water Works, Indiana and Evansville, Illinois), demonstrating continuing problems with atrazine contamination. Table 2 shows the water systems with running annual averages above 3 ppb in either the raw or the finished water.

As we found in our analysis of the 2003 and 2004 monitoring data, some utilities are effectively treating the atrazine in their water, while others are not. For example, in the Mt. Orab water system in Brown County, Ohio, there was 227 ppb of atrazine in the raw water on May 23, 2006. Due to a history of high levels of atrazine in Sterling Run Creek (the source water), Mt. Orab tests the water from the creek before pumping it into its reservoirs to avoid water with a high atrazine content. As a result of this testing and the installation of activated carbon filters, the atrazine concentration in the finished water has remained low – below 0.3 ppb.[10] When on May 23, 2006 the 227 ppb spike was detected in the raw water, the finished water had no detectable atrazine.

Other water systems also are successfully reducing high levels of atrazine in their water. For example, the Nashville water system in Washington County, Illinois uses powdered activated carbon to remove atrazine.[11] The monitoring data show that Nashville's raw water has had high levels of atrazine over the years, but atrazine levels in the system's finished water have remained below 1 ppb (see Figure 2).

Table 2. Water systems with annual running averages of atrazine above 3 ppb in raw or finished water, 2005 – 2008

Name of monitoring site	State	County	Population Served[8, 9]	Highest running annual average (ppb)	
				Raw Water	Finished Water
Mt. Orab Village Public Water System	Ohio	Brown	3,565	19.59	0.12
Wyaconda	Missouri	Clark	385	11.24	4.05
Piqua City Public Water System	Ohio	Miami	20,883	7.09	3.11
Versailles Water Works*	Indiana	Ripley	1,784	5.24	4.83
Nashville Water Plant	Illinois	Washington	3,320	4.79	0.15
Mt. Olive Water Works	Illinois	Macoupin	2,150	4.45	2.59
Clermont Co. Water	Ohio	Clermont	101,402	4.15	1.15
Evansville*	Illinois	Randolph	740	4.08	4.44
Kaskaskia Water District	Illinois	St. Clair	12,586	4.08	1.29
Blanchester Village	Ohio	Clinton	4,500	3.95	6.67
Wayne City	Illinois	Wayne	1,370	3.70	0.66
Carthage Public Utilities	Illinois	Hancock	2,725	3.64	0.84
Winterset Water Treatment Plant	Iowa	Madison	4,768	3.40	0.56
McClure Water Treatment Plant	Ohio	Henry	850	3.23	2.74
Coulterville Water Treatment Plant	Illinois	Randolph	1,300	3.02	1.09
Beloit Water Department	Kansas	Mitchell	3,639	2.21	3.48

*This system also had a running annual average above 3 ppb in 2003 or 2004.

Figure 2. Atrazine concentration in raw and finished water, Nashville water system (Illinois), 2005 – 2008

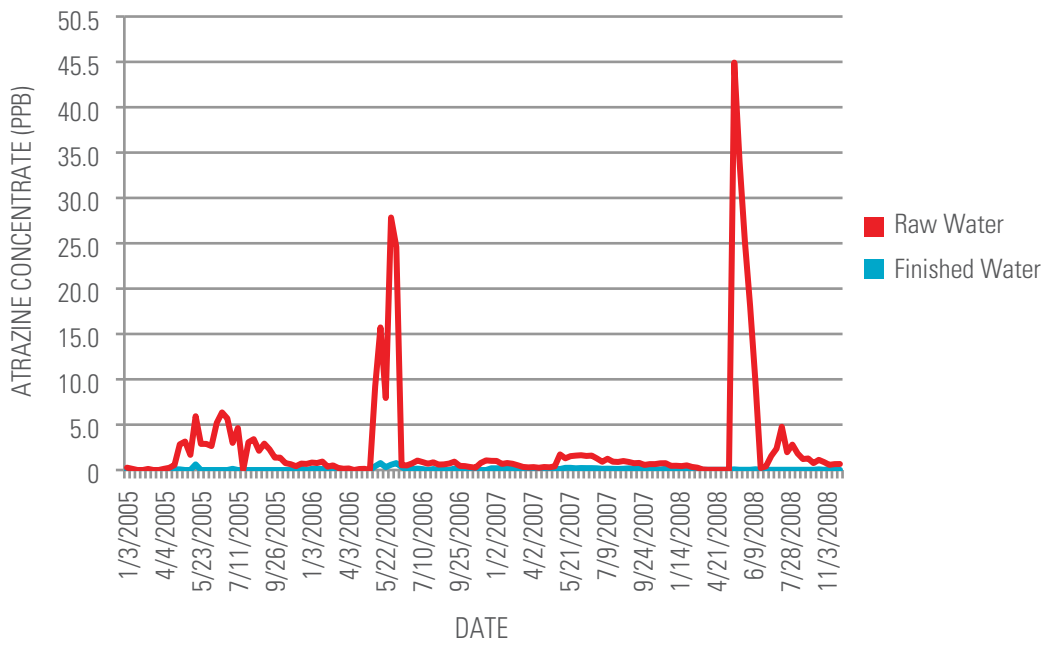


Figure 3. Atrazine concentration in raw and finished water, Blanchester water system (Ohio), 2005 – 2008

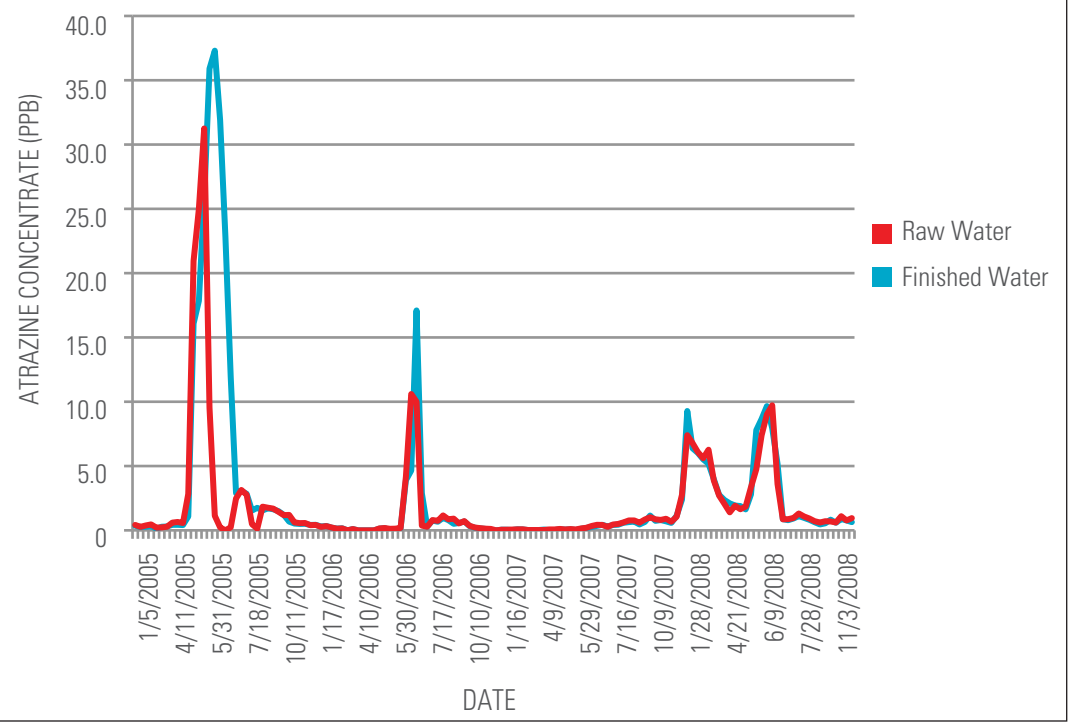


Table 3. Water systems with the highest peak atrazine concentration in raw water

Public water system	State	Date	Maximum Atrazine Concentration (ppb)		Concentration of next sample in raw water (ppb)*	Number of weeks that concentration exceeded 3 ppb
			Raw water	Finished water		
Mt. Orab Village Public Water System	Ohio	5/23/2006	227.00	0.00	65.6	2 weeks
Piqua City Public Water System	Ohio	4/25/2005	84.80	59.57	35.29	12 weeks
Kaskaskia Water District	Illinois	4/25/2005	57.98	14.73	13.32	6 weeks
Baxter Springs Water Treatment Plant	Kansas	4/25/2005	56.74	4.60	5.55	1 week
Nashville Water Plant	Illinois	5/12/2008	44.92	0.07	34.0	4 weeks
Mc Clure Water Treatment Plant	Ohio	6/3/2008	42.89	33.83	13.26	4 weeks
Monroeville Village	Ohio	6/23/2008	37.28	0.03	5.58	1 week
Coulterville Water Treatment Plant	Illinois	6/9/2008	35.50	1.88	0.83	2 weeks prior to peak
Thibodeaux Water Works	Louisiana	5/31/2005	34.75	11.25	0.38	—
Mt. Olive Water Works	Illinois	6/9/2008	33.40	16.47	16.54	10 weeks

* All readings taken 7 days after the peak, except Mt. Orab which was taken 8 days later.

Unfortunately, not all systems have such effective treatments for atrazine. For example, the concentration of atrazine in the raw water and the finished water very closely mirrored one another in the water system in Blanchester, Ohio (see Figure 3). Four years of sampling data indicate that overall the system is not effectively treating for atrazine.

It is also interesting to note that some systems had running annual average concentrations in finished water that were higher than the concentrations in raw water (such as the Blanchester water system). This result may be due to the fact that samples of raw water are taken at different times than samples of finished water, so that high spikes in raw water are not detected, which further underscores that more frequent testing would catch high peak concentrations that may otherwise be missed.

To see the sampling results for all drinking water systems monitored between 2005 and 2008, see the Appendix.

High Peak Concentrations of Atrazine Endanger Human Health

High, seasonal peak concentrations of atrazine are just as important—if not more so—than the annual average level. Exposure to high levels of hormone-disrupting chemicals such as atrazine during key windows of development are associated with permanent developmental and reproductive effects.[12, 13, 14] Therefore, atrazine spikes in the finished water of public water systems—such as the spikes shown on Table 4—are a public health concern, especially to vulnerable populations, such as fetuses, infants, and children.

Table 4. Water systems with the highest peak atrazine concentration in finished water

Public water system	State	Date	Maximum atrazine concentration in finished water (ppb)	Next reading	Number of weeks that concentration exceeded 3 ppb
Piqua City Public Water System	Ohio	4/25/2005	59.57	27.09	1 week
Beloit Water Department	Kansas	5/27/2008	41.61	9.72	1 week
Blanchester Village Public Water System	Ohio	6/6/2005	37.30	31.90	3 weeks
Mc Clure Water Treatment Plant	Ohio	6/3/2008	33.83	11.95	3 weeks
Versailles Water Works	Indiana	5/23/2005	30.48	28.95	7 weeks
Flora Water Treatment Plant	Illinois	5/23/2005	30.48	6.67	1 week
Evansville	Illinois	5/2/2005	25.75	9.57	4 weeks
Logansport Municipal Utility	Indiana	6/2/2008	20.94	6.90	1 week
Caney Water Treatment	Kansas	4/10/2006	19.90	3.24	1 week
Delaware Water Plant	Ohio	5/2/2005	19.33	5.40	1 week

As noted earlier, high peak concentrations of atrazine in the finished water are not necessarily detected by the "routine" monitoring required by the EPA to show compliance with drinking water regulations. As a result, some systems that are shown to comply with the federal standard may actually have annual concentrations of atrazine that exceed the limit. For example, in both 2005 and 2006, the state of Ohio reported no violations of the federal drinking water standard for atrazine; however, based on the more frequent monitoring under the Atrazine Monitoring Program, two different systems in Ohio had running annual average concentrations of atrazine that exceeded 3 ppb.[15] Therefore, showing compliance with the federal standard does not necessarily indicate that a drinking water system provides water that has an annual average concentration below 3 ppb.

Continued Atrazine Use Brings High Economic Costs

As discussed in our 2009 report, atrazine use brings little economic benefit to farmers. A study by the U.S. Department of Agriculture suggests that if atrazine were banned in the United States, the loss of corn yields would be only about 1.19 percent, while corn acreage would be reduced by only 2.35 percent.[16,17] An analysis by Tufts University economist Dr. Frank Ackerman of three other studies that estimated higher corn losses found them to be limited by serious methodological problems.[18] Additionally, Ackerman found that despite a ban on the use of atrazine in Italy and Germany (both corn-producing nations) since 1991, neither country has recorded any significant economic effects. Indeed, there was "no sign of [corn] yields dropping in Germany or Italy after 1991, relative to the U.S. yield—as would be the case if atrazine were essential" and "[f]ar from showing any slowdown after 1991, both Italy and (especially) Germany show faster growth in harvested areas after banning atrazine than before." Based on this analysis, Ackerman concluded that if "the yield impact is on the order of 1%, as USDA estimated, or close to zero, as suggested by the newer evidence discussed here, then the economic consequences [of phasing out atrazine] become minimal."[19]

The cost of reducing the negative impacts stemming from atrazine use, however, is not trivial. Installing additional water treatment systems and taking other measures to reduce atrazine contamination could overwhelm the already overtaxed resources of cities, towns, and utilities charged with providing safe and clean water to the public. Water systems facing elevated levels of atrazine may need to install granulated

activated carbon (GAC) filters to reduce levels of this pesticide, which can be a large expense. For example, the Mt. Orab water system in Ohio produces 372,000 gallons of drinking water per day for about 3,600 people. It has experienced the highest atrazine spikes in its source water among those systems analyzed in this report. To treat this water, Mt. Orab spends $50,000 per year just on carbon replacement for its GAC filters; that figure does not include the cost of purchasing the system or performing other needed maintenance.[20] This level of expense may be expected for any system dealing with atrazine contamination. The small systems taking water from areas surrounded by agricultural lands on which atrazine is used may be most vulnerable to the contamination and be faced with paying these high costs.

CHAPTER 4

Recommendations for Curbing Atrazine Contamination

The contamination of watersheds and drinking water with atrazine around the United States continues to be a problem. Exceedingly high levels are still being detected, levels which are likely having significant effects on wildlife populations and potentially adverse health effects on humans. The few benefits of using atrazine combined with the high cost of treating atrazine-contaminated water further reinforces NRDC's original recommendations.

Recommendation #1: The U.S. EPA Should Phase Out the Use of Atrazine

Atrazine is not agriculturally necessary and does not produce economic benefits that justify its ecological and human health risks. In 2006, the EPA chose not to prohibit the use of atrazine, opting instead to require more monitoring. The results are in, and they show that atrazine contamination of drinking water sources is pervasive and occurs at concentrations that many affected water systems are unable to reduce to safe levels. In early 2010, the EPA began reexamining the data on atrazine. The EPA should take the next logical step to protect public health by removing atrazine from store shelves and curbing its release into our soil and waterways.

Recommendation #2: Farmers Should Be Encouraged to Take Interim Steps to Reduce Their Atrazine Use

Farmers often choose to use atrazine and other pesticides not because they are more effective than other farming methods, but because they are familiar and cheap. Fortunately, there are concrete steps that many farmers are already taking to reduce their use of atrazine and other pesticides. Some farmers are reporting to us that they routinely use only half the amount of atrazine that the label allows, and it is just as effective. Encouraging farmers to follow these leaders and reduce atrazine application rates, especially by using targeted spraying or by applying atrazine in a narrow band in crop rows, is both effective and a money-saver.[1] Other sustainable practices, such as applying atrazine after the corn has emerged, could reduce runoff by half.[2]

Using Integrated Pest Management (IPM) approaches for weed management relies on weed prevention, field monitoring, and the use of effective lower risk control methods. Farmers set an action threshold—the point at which the number of weeds reaches a level that indicates that control is necessary. Control methods are utilized only when the action threshold is exceeded. Controls could include mechanical and natural methods of weed control, and

low-risk pesticides. Conventional pesticides are used only as a last resort.[3] IPM techniques may include:

- **Cover Crops**: Winter cover crops are a prevention strategy that can greatly reduce weed growth by competing with weeds for light, water, and nutrients, and protect soil from erosion. Legumes used as cover crops can also increase nitrogen in the soil.[4]
- **Mechanical Weed Control Methods**: Rotary hoes can be used after weed seeds have germinated, but before the weeds emerge, to significantly reduce weed growth; cultivators can remove emergent weeds before they become established. [5]
- **Delayed Fertilizer Application**: Delaying application of half of the fertilizer used on corn crops until after the ears emerge can deprive weeds of nutrients during key periods of growth, while ensuring that these nutrients are available to the crop when it is best able to absorb them.[6,7]
- **Intercrops**: Alternating rows of different crops helps reduce weeds and results in higher crop yields.[8]
- **Crop Rotation**: Weed density and pesticide use can be reduced substantially by shifting from a two-year corn/soy rotation, typical of Midwestern agriculture, to a multispecies three- or four-year rotation that adds species such as alfalfa and oat.[9, 10]

Recommendation #3: The EPA Should Monitor All Vulnerable Watersheds and Require All Future Monitoring Plans to Identify Worst Case Scenarios

Although the EPA identified 1,172 watersheds that are at highest risk from atrazine contamination, the monitoring data set included samples from only twenty watersheds. Any future monitoring plans should be designed to identify the worst case scenarios occurring in vulnerable watersheds and in public water systems. Monitoring programs should be designed to increase the chances of detecting contamination if it exists. This would include requiring samples to be taken within a certain time after big rainstorms and after fields have been treated with atrazine, which would increase the likelihood of determining the severity of the atrazine problem.

Recommendation #4: The EPA Should Publish Timely Monitoring Results for Each Watershed and Public Water System Sampled Online in a User-Friendly Format

Monitoring results on the watersheds and the public water systems that were sampled under the two different monitoring programs were first made available to NRDC through Freedom of Information Act requests and through litigation by NRDC. However, the public has a right to know if there is an atrazine problem which they must treat, especially people who live downstream of atrazine-treated fields and who may have sensitive individuals—such as pregnant women and infants—in their households. A publicly available website with a searchable database posting sampling data as they are analyzed, or even regular reports about spikes of atrazine contamination, similar to the interactive map produced by NRDC,[11] would make this information more accessible to the public than the EPA's current method of posting large data files in an EPA docket. Furthermore, the data should be presented comprehensively, rather than just in summary form. For example, drinking water systems that have been monitored must be identified by name, along with the monitoring results.

Recommendation #5: The Public Should Use Home Water Filtration Systems and Demand Transparency of Information from Their Water Utilities

NRDC recommends that consumers who are concerned about atrazine in their drinking water use a water filter certified by NSF International to meet NSF/American National Standards Institute (ANSI) Standard 53 for atrazine reduction. This standard includes some faucet-mounted charcoal filters. While filters that meet this certification do not always eliminate atrazine entirely, certified filters earning the NSF certification are able to reduce atrazine levels in drinking water from 9 ppb of atrazine to 3 ppb.[12]

Appendix: Still Poisoning the Well

Presented here are all the results from our analysis of the Atrazine Monitoring Program broken down by state. Samples of raw and finished water were taken from each system throughout the monitoring period and analyzed for atrazine concentration. We have reported on the highest annual running average calculated for each system in both the raw water and the finished water. We have also calculated the highest concentration of atrazine detected throughout the monitoring period in both the raw water and the finished water.

Because it is based on a running annual average, high peak concentrations of atrazine may not result in a violation of the federal standard if the remainder of the year had low or no detections of atrazine.

Atrazine concentrations in public water systems, 2005 - 2008

Name of monitoring site[1]	State	Population served[2]	Maximum atrazine concentration (ppb)		Years sampled	Number of sampling dates
			Raw Water	Finished Water		
Stockton East	CA	50	0.025	0.025	2007	27
Stockton East New Melones Reservoir	CA	50	0.025	0.025	2007	14
Sumner Hills	CA	N/A	0.025	0.025	2007	29
Belle Glade	FL	N/A	1.22	1.31	2007	38
Lee County	FL	224,840	0.98	0.09	2007	37
Peace River	FL	3,301	0.12	0.05	2007	38
Punta Gorda	FL	29,561	0.34	0.27	2007	37
Centerville Municipal Water Works	IA	5,924	2.18	49	2005 - 2006	49
Chariton Municipal Water Works	IA	4,573	5.23	1.75	2005 - 2008	132
Creston (12 Mile Lake)	IA	7,597	2.93	—	2005; 2008	20
Creston (3 Mile Lake and Finished)	IA	7,597	3.8	3.49	2005 - 2008	133
Lamoni Municipal Utilities	IA	2,554	4.79	1.7	2005 - 2006	65
Leon Water Works	IA	1,983	2.02	1.02	2005 - 2006	65
Montezuma Municipal Water	IA	1,457	3.11	0.59	2005 - 2008	138
Osceola Municipal Water Works	IA	4,659	5.82	1.54	2005 - 2008	130
Rathbun Regional Water Association	IA	27,300	1.37	1.2	2005 - 2006	65
Winterset Water Treatment Plant	IA	4,768	28.25	4.93	2005 - 2008	136
Aqua Illinois, Inc.	IL	38,000	9.11	6.81	2005 - 2008	137
Ashland	IL	1,361	1.72	1.3	2005 - 2008	133
Carlinville Water Works	IL	5,685	10.66	5.1	2005 - 2008	128

1 Systems reported concentrations from different water sources separately, so some systems may be listed more than once here.
2 Source: U.S. EPA. Safe Drinking Water Information System (SDWIS). Available at: http://www.epa.gov/enviro/html/sdwis/sdwis_ov.html.

Name of monitoring site[1]	State	Population served[2]	Maximum atrazine concentration (ppb)		Years sampled	Number of sampling dates
			Raw Water	Finished Water		
Carthage Public Utilities	IL	2,725	10.23	2.27	2005 - 2006	64
Centralia Water Treatment Plant	IL	14,274	9.39	6.4	2005 - 2008	138
Coulterville Water Treatment Plant	IL	1,300	35.5	2.64	2005 - 2008	137
Evansville	IL	740	29.37	25.75	2005 - 2008	129
Farina Water Treatment Plant	IL	600	4.21	3.48	2005 - 2008	142
Flora Water Treatment Plant	IL	5,675	27.4	30.48	2005 - 2008	130
Gillespie Water Treatment Plant	IL	3,646	14.3	2.78	2005 - 2008	136
Greenfield Water Treatment Plant	IL	1,200	0.77	0.63	2005 - 2006	64
Highland Water Treatment Plant	IL	9,000	1.47	0.5	2005 - 2006	64
Hillsboro	IL	5,759	3.98	2.98	2007 - 2008	76
Hillsboro, Glen Shoals	IL	5,759	4.6	2.8	2005 - 2006	50
Hillsboro, Lake	IL	5,759	0.2	0.13	2006	1
Holiday Shores Sanitary District	IL	3,387	1.21	1.27	2005 - 2006	65
Kaskaskia Water District	IL	N/A	57.98	14.73	2005 - 2008	135
Kinkaid Area Water System	IL	N/A	1.95	1.79	2005 - 2008	135
Mattoon	IL	19,000	2.74	3.04	2007 - 2008	57
Mt. Olive Water Works	IL	2,150	8.61	4.59	2007	35
Mt.Olive, New Lake	IL	2,150	0.84	—	2005	4
Mt.Olive, Old Lake & Finished	IL	2,150	33.4	16.47	2005 - 06; 2008	102
Nashville Water Plant	IL	3,320	44.92	0.77	2005 - 2008	136
New Berlin	IL	1,050	0.93	0.91	2005 - 2008	110
Otter Lake Water Commission	IL	1,251	3.78	2.68	2005 - 2006	63
Palmyra-Modesto Water Commission	IL	70	2.38	1.24	2005 - 2006	65
Paris	IL	9,077	26.1	6.75	2005 - 2008	130
Patoka (East Reservoir & Mid-Process Finished)	IL	731	3.62	1.34	2006	18
Patoka (North Fork Kaskaskia & Finished)	IL	731	14.87	1.24	2006	18
Patoka (West Reservoir & Purchased Finished)	IL	731	4.88	0.81	2006	17
Pittsfield Water Treatment Plant	IL	4,250	2.98	0.24	2005 - 2006	64
Salem WTP	IL	9,000	6.69	3.81	2005 - 2006	65
Springfield City Water Light and Power	IL	128,439	1.16	1.16	2005 - 2006	65
Vermont Water Treatment Plant	IL	800	10.72	2.44	2005 - 2008	137

1 Systems reported concentrations from different water sources separately, so some systems may be listed more than once here.
2 Source: U.S. EPA. Safe Drinking Water Information System (SDWIS). Available at: http://www.epa.gov/enviro/html/sdwis/sdwis_ov.html.

Name of monitoring site[1]	State	Population served[2]	Maximum atrazine concentration (ppb)		Years sampled	Number of sampling dates
			Raw Water	Finished Water		
Waverly	IL	1,346	9.33	6.79	2005 - 2008	120
Wayne City (Skillet Fork Creek)	IL	1,370	20.6	1.66	2005 - 2008	133
Batesville Water Treatment Plant	IN	5,856	6.24	2.86	2005 - 2008	136
Bedford Water Department	IN	14,000	28.07	8.37	2005 - 2008	136
Fort Wayne (Three River Filtration Plant)	IN	250,000	6.14	4.06	2005 - 2008	129
Indianapolis (Eagle Creek Water Treatment Plant)	IN	781,896	6.87	4.86	2005 - 2006	68
Jasper Municipal Water	IN	12,500	3.01	2.48	2005 - 2008	136
Lake Santee	IN	N/A	15.97	10.54	2005 - 2006	70
Logansport Special Purpose	IN	12,861	27.45	20.94	2005 - 2008	136
Mitchell	IN	4,800	21.06	18.07	2005 - 2008	122
North Vernon	IN	6,500	9.96	8.34	2007 - 2008	49
Stucker Fork Water Treatment Plant	IN	14,000	20.5	10.3	2005 - 2008	144
Versailles Water Works	IN	1,784	29.3	30.48	2005 - 2008	126
Westport Water Company	IN	1,600	1.97	2.66	2005 - 2008	128
Winslow Water Works	IN	881	13.7	13	2005 - 2008	133
Altoona	KS	474	9.79	12.9	2005 - 2008	130
Atchison	KS	10,154	6.78	9.48	2005 - 2008	134
Baxter Springs	KS	4,600	56.74	13.41	2005 - 2008	131
Beloit Water Department	KS	3,639	31.88	31.13	2005 - 2007	103
Burlington City Water Works	KS	2,721	5.1	4.34	2005 - 2008	133
Caney	KS	1,994	8.48	19.9	2005 - 2008	122
Carbondale	KS	1,440	6.28	2.05	2005 - 2008	132
Chanute	KS	8,887	5.43	6.51	2006 - 2008	89
Chetopa	KS	1,234	5.74	6.65	2007 - 2008	41
Ellsworth RWD #1	KS	2,626	4.86	3.71	2005 - 2008	131
Emporia	KS	26,456	4.1	1.64	2005 - 2008	136
Erie	KS	1,167	8.54	9.18	2005 - 2008	134
Franklin County Rural Water District #6	KS	2,400	5.91	5.59	2005 - 2008	134
Harveyville	KS	252	0.89	1.17	2006 - 2008	42
Kansas City Board of Public Utilities	KS	164,462	2.53	2.54	2005 - 2008	135
LaCygne	KS	1,155	4.53	3.77	2006 - 2008	88
Linn Valley Lakes POA	KS	146	0.84	0.80	2005 - 2008	82

1 Systems reported concentrations from different water sources separately, so some systems may be listed more than once here.
2 Source: U.S. EPA. Safe Drinking Water Information System (SDWIS). Available at: http://www.epa.gov/enviro/html/sdwis/sdwis_ov.html.

Name of monitoring site[1]	State	Population served[2]	Maximum atrazine concentration (ppb)		Years sampled	Number of sampling dates
			Raw Water	Finished Water		
Miami Co. Rural Water District #2	KS	8,631	2.97	2.13	2005 - 2008	133
Milford	KS	444	2.74	2.73	2005 - 2008	138
Mitchell Co. Rural Water District #2	KS	1,291	2.86	2.86	2005 - 2008	131
Olathe (Composite of Collector Wells)	KS	111,334	2.06	--	2005 - 2008	126
Olathe (Kansas River and Finished)	KS	111,334	3.45	3.23	2005 - 2008	132
Olathe (WTP1)	KS	111,334	5.1	0.97	2005	17
Osage Co. Rural Water District #3	KS	900	16.18	8.79	2005 - 2008	131
Osawatomie	KS	4,616	15.43	14.5	2005 - 2008	135
Paola	KS	5,292	2.17	2.12	2005 - 2008	135
Public Wholesale WSD #12	KS	N/A	2.35	1.66	2005 - 2008	135
Public Wholesale WSD #5	KS	N/A	4.53	4.3	2005 - 2008	132
Richmond	KS	514	15.85	13.36	2005 - 2008	116
Salina	KS	46,140	2.42	0.86	2007 - 2008	53
St. Paul	KS	657	8.6	9.77	2005 - 2008	130
Topeka Water Treatment Plant	KS	121,946	6.52	6.13	2005 - 2008	134
Valley Falls	KS	1,209	8.22	7.04	2005 - 2007	137
Leitchfield Water Works	KY	9,309	4.8	2.6	2005 - 2008	127
Livermore Green River	KY	2,168	2.48	--	2006 - 2007	25
Livermore Rough River & Finished	KY	2,168	5.18	5.2	2006 - 2007	57
Marion, Lake George & Finished	KY	3,033	1.12	0.48	2005 - 2008	133
Marion, Old City Lake	KY	3,033	1.69	0.025	2005 - 2008	120 (only 1 for finished water)
Webster Co. Water District	KY	4,386	4.74	4.95	2005 - 2008	137
E. Jefferson Water Works District #1	LA	308,362	1.9	2.38	2005 - 2008	171
Iberville Water District #3	LA	9,072	13.88	16.13	2005 - 2008	178
LaFourche Water Dist. #1	LA	78,760	6.71	9.11	2005 - 2008	177
Thibodeaux Water Works	LA	15,810	34.75	11.25	2005 - 2008	177
Bucklin Water Department	MO	524	1.62	0.25	2005 - 2008	118
Cameron Light & Power	MO	9,788	1.61	0.59	2005 - 2008	134
Clarence Cannon WWC, United Water	MO	N/A	6.45	1.64	2005 - 2006	66
Concordia Water Treatment Plant	MO	2,360	7.94	5.62	2005 - 2008	104
Creighton	MO	290	0.31	0.1	2005 - 2006	40

1 Systems reported concentrations from different water sources separately, so some systems may be listed more than once here.
2 Source: U.S. EPA. Safe Drinking Water Information System (SDWIS). Available at: http://www.epa.gov/enviro/html/sdwis/sdwis_ov.html.

Name of monitoring site[1]	State	Population served[2]	Maximum atrazine concentration (ppb)		Years sampled	Number of sampling dates
			Raw Water	Finished Water		
Drexel	MO	1,200	2.04	1.27	2006 - 2008	87
Hannibal Water Treatment Plant	MO	17,596	8.22	5.79	2005 - 2008	133
Harrison County #1	MO	900	1.48	1.43	2006 - 2008	80
Jamesport Water Treatment Plant	MO	600	2.95	2.2	2005 - 2008	137
La Plata Water Treatment Plant	MO	1,401	2.26	1.71	2005 - 2006	46
Marceline Water Treatment Plant	MO	2,548	1.67	0.53	2005 - 2008	125
Maryville Water Treatment Plant	MO	9,872	5.54	5.02	2005 - 2008	133
Maysville	MO	1,100	1.38	1.36	2006 - 2008	77
Middlefork Water Company	MO	N/A	2.81	2.32	2005 - 2008	135
Monroe City (Route J Lake)	MO	2,700	4.6	0.025	2005 - 2008	132
Monroe City (S. Lake)	MO	2,700	1.43	0.68	2005 - 2007	104
Monroe City Finished	MO	2,700	4.35	1.95	2008	33
Shelbina (Salt River)	MO	1,640	13.12	—	2005 - 2008	136
Shelbina (Shelbina Lake and Finished)	MO	1,640	6.9	0.19	2005 - 2008	136
Smithville Water Treatment Plant	MO	9,408	2.64	1.54	2005 - 2008	136
Unionville Water Treatment Plant (Thunderhead Lake or Lake Mahoney and Finished)	MO	2,000	2.96	0.65	2005 - 2006	62
Vandalia Water Treatment Plant	MO	2,863	10.15	2.23	2005 - 2008	133
Wyaconda Water Treatment Plant	MO	385	23.01	16.56	2005 - 2008	188
Johnston	NC	62,230	0.05	0.05	2006 - 2007	46
Monroe (John Glenn WTP)	NC	32,454	3.94	2.82	2005 - 2008	130
South Granville	NC	10,467	0.27	0.23	2008	22
Alliance Water Treatment Plant	OH	23,000	3.73	0.65	2005 - 2008	128
Blanchester	OH	4,500	31.25	37.3	2005 - 2008	136
Bowling Green Water Treatment Plant	OH	30,000	29.17	0.51	2005 - 2008	135
Cinnamon Lake Utility Co.	OH	1,522	2.18	1.99	2005 - 2008	136
Clermont Co. Water, BMWTP	OH	101,402	10.85	2.68	2005 - 2008	136
Defiance	OH	17,000	15.8	18.5	2005 - 2008	132
Delaware Water Plant	OH	33,480	30.43	19.33	2005 - 2008	136
Lake of the Woods Water Company	OH	475	8.09	4.9	2005 - 2008	126
Lima	OH	74,750	2.49	1.75	2005 - 2008	135

1 Systems reported concentrations from different water sources separately, so some systems may be listed more than once here.
2 Source: U.S. EPA. Safe Drinking Water Information System (SDWIS). Available at: http://www.epa.gov/enviro/html/sdwis/sdwis_ov.html.

Name of monitoring site[1]	State	Population served[2]	Maximum atrazine concentration (ppb)		Years sampled	Number of sampling dates
			Raw Water	Finished Water		
McClure Water Treatment Plant	OH	850	42.89	33.83	2005 - 2008	112
Monroeville	OH	1,433	21.84	0.28	2005 - 2007	103
Monroeville Reservoir & Finished	OH	1,433	0.79	0.025	2008	32
Monroeville W Branch Huron	OH	1,433	37.28	—	2008	32
Mt.Orab (Mt. Orab Reservoir and Finished)	OH	3,565	11.31	0.27	2005 - 2008	137
Mt.Orab (Sterling Run Creek)	OH	3,565	227	—	2005 - 2008	90
Napoleon	OH	9,318	31.39	10.23	2005 - 2008	137
New Washington Water Plant	OH	987	3.26	2.62	2005 - 2008	123
Newark Water Works	OH	48,000	18.05	6.67	2005 - 2008	136
Norwalk Water Treatment Plant	OH	16,200	6.76	0.81	2005 - 2008	134
Ottawa	OH	4,367	1.63	1.37	2005 - 2008	134
Piqua (Gravel Pit)	OH	20,500	1.52	—	2005 - 2008	136
Piqua (Miami River)	OH	20,500	32.85	—	2005 - 2008	136
Piqua Swift Run Lake & Finished	OH	20,500	84.8	59.57	2005 - 2008	136
Shelby (Reservoir 2 and Finished)	OH	9,860	8.14	2.9	2005 - 2008	131
Shelby (Reservoir 3)	OH	9,860	2.25	—	2005 - 2008	129
Upper Sandusky	OH	6,600	1.74	1.82	2005 - 2008	122
Waynoka Regional Water	OH	1,400	5.39	2.45	2005 - 2008	138
Wilmington	OH	11,921	3.59	1.21	2005 - 2006	66
Wilmington (Caesar Creek Reservoir or Gowan Lake Reservoir and Finished)	OH	11,921	4.88	2.78	2005 - 2006	67
Aquilla Water Supply District	TX	N/A	4.00	2.33	2005 - 2006	59
BRA Granger Lake	TX	N/A	1.87	1.53	2005 - 2008	131
Brazosport Water Authority	TX	N/A	6.57	9.42	2005 - 2008	123
Cameron	TX	6,624	4.00	6.32	2006 - 2008	75
Cooper Water Treatment Plant	TX	5,184	4.35	4.18	2005 - 2008	117
Corsicana	TX	28,500	3.25	3.25	2005 - 2006	64
Crosby	TX	4,644	1.59	1.73	2008	19
Crosby, Gulf Coast Aquifer Wells	TX	4,644	1.71	—	2008	6
Ennis	TX	37,901	3.62	1.92	2005 - 2008	137
Marlin Water Treatment Plant	TX	6,200	3.99	3.77	2005 - 2006	64
Midlothian Water Treatment Plant	TX	25,515	2.71	2.93	2005 - 2008	137
Waxahachie Water Treatment Plant	TX	55,900	1.71	1.79	2005 - 2008	124

1 Systems reported concentrations from different water sources separately, so some systems may be listed more than once here.
2 Source: U.S. EPA. Safe Drinking Water Information System (SDWIS). Available at: http://www.epa.gov/enviro/html/sdwis/sdwis_ov.html.

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EXECUTIVE SUMMARY

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CHAPTER 1

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ATTACHMENT 17

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It's not easy being green: are weed-killers turning frogs into hermaphrodites?

Souder, William

In the summer of 1997, Tyrone Hayes, a biologist at the University of California, Berkeley, accepted what seemed a harmless offer to join a panel of eight other scientists investigating the safety of the common weed-killer atrazine. The panel had been commissioned by atrazine's inventor and primary manufacturer, the Swiss-based chemical giant then called Novartis and since renamed Syngenta. The company wanted to know if its product threatened "non-target" organisms, including fish, reptiles, and amphibians--creatures whose fate had remained largely unexplored through the half century in which atrazine had become the most heavily used herbicide in the United States as well as one of its most widespread environmental contaminants.

Hayes himself was acutely interested in discovering the causes of a global decline in frog populations that had worried scientists since the early 1990s. Many of the hormones and genes that regulate reproduction and development and metabolism in frogs perform similar functions in people, making frogs important proxies for humans--nature's test animals in a changing world. Syngenta's concern was different. The Environmental Protection Agency had been ordered by Congress to "reregister" atrazine as part of a program to subject a large number of older pesticides to current safety testing, a process that required considerable new data.

Initially, Hayes was asked only to review the scientific literature for studies involving atrazine and frogs. The review turned up nothing, so Hayes designed an experiment to test atrazine directly on the animals. "I honestly thought that the compound wouldn't do anything," Hayes says. "There was no basis that I knew of for a hypothesis that it would. My concern was how it would look to my colleagues. Would it look like I had prostituted myself to a company to do studies that weren't going to produce anything?" Hayes took a vote among his students in the Department of Integrative Biology, some of whom were so anticorporate, he says, that they wouldn't go to Starbucks. But they agreed to do the experiment. Over the course of the next two and a half years, Syngenta paid Hayes's lab $250,000.

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The experiment was similar to ones Hayes had performed many times before. Newly hatched tadpoles were reared in water containing atrazine in amounts ranging from .01 to 25 parts per billion (ppb) until the animals completed metamorphosis. The test animal was the African clawed frog, a species known as the "lab rat of amphibians" and typically referred to by its generic name, Xenopus. Once used in human pregnancy testing, Xenopus is easier to rear than native North American species, largely because it is entirely aquatic, can be readily force-bred, grows quickly through well-defined stages, and will eat almost any commercial animal feed. Hayes gives his tadpoles Purina Rabbit Chow.

In March 1999, Hayes and his students divided 900 Xenopus tadpoles among thirty small aquariums. Half of the tanks contained atrazine; the rest--the control tanks--did not. All the tanks were coded, so neither Hayes nor his students knew which animals were swimming in what dose. Every three days, the tanks were cleaned and the solutions replaced. After forty days, the tadpoles had become frogs. When Hayes examined the frogs, all the control animals were normal. So were all the females. But among the males that had been exposed to atrazine at concentrations of 1 ppb or more, about 80 percent had smaller than expected laryngeal dilator muscles--puny voice boxes.

Laryngeal muscle size is an important secondary sexual characteristic in frogs; male frogs rely on the strength and pitch of their mating calls to attract females. Male bullfrogs sometimes sit near a spring at the edge of a pond where the inflow of colder water constricts the larynx and lowers the tone of their call.

Examining the frogs more closely, Hayes was surprised to discover that about a third of the male frogs exposed to atrazine also had abnormal reproductive organs. Some had malformed or multiple sets of testes. Others had both testes and ovaries, sometimes in odd numbers. The co-occurrence of testes and ovaries is rare in vertebrates and rarer still in Xenopus. Yet in Hayes's experiment this morphology had been elicited at concentrations as low as .1 ppb, a tenth of the amount that altered their voice boxes. Such a dose is equivalent to a grain of salt dissolved in a ten-gallon aquarium. To put it another way, the federally established "safe" limit for atrazine in human drinking water is 3 ppb, thirty times the dose that turned some of Hayes's frogs into hermaphrodites.

Tyrone Hayes is five feet three and sturdy from years of predawn cycling and running. He has shoulder-length black hair, which he wears braided or in a ponytail, or, sometimes, swept back from his face in a stiff mane. Around the lab he's usually in shorts and a T-shirt, but for speaking engagements and faculty meetings, he favors a black suit, an iridescent tie, and dangly earrings. Hayes was born in 1967, in Columbia, South Carolina, where his father is a carpet layer. He attended Harvard, where he earned a summa cum laude for a thesis on how temperature influences development in wood frogs. In graduate school, at Berkeley, Hayes studied endocrinology, investigating the impact of environmental factors on frog hormones. At thirty-two, he became the youngest tenured professor in the department's history and was named a full professor three years later.

Hayes says that he was naive about how his findings would be received. After reporting his discovery to the other panelists studying atrazine, Hayes argued with them and with Syngenta for months about what to do next. There were protracted discussions about the statistical relevance of the voice-box data and

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disagreements over the pace of follow-up studies. Hayes was asked for repeated revisions of the "final" report on his results. He saw all of this as an effort to discourage him from publishing his findings. In November 2000 he quit the panel. In his letter of resignation he complained that were he to remain on the team, "recent history suggests that I will spend a great deal of effort preparing reports that will not be finalized in a timely manner, let alone published." He added, "It will appear to my colleagues that I have been part of a plan to bury important data."

In fact, Hayes's contract with Syngenta's atrazine panel did not prevent him from publishing his research. There was, however, an implicit understanding that panel members--in addition to scientists at Syngenta--would review one another's work. Hayes worried that such consultation, which had already slowed him, would eventually paralyze his research. Hayes's colleagues, meanwhile, wondered at his impatience. "Tyrone is an interesting person," says Keith Solomon, a professor of environmental biology at the University of Guelph, in Ontario, who contines to serve on Syngenta's panel. "But he's in a hurry."

In January 2001 staff scientists from Syngenta visited Hayes at Berkeley in an attempt to get him to rejoin the team. The meeting, which included discussions of a direct arrangement with Syngenta in which Hayes would continue his work, did not go well. "I'm certain they would have had control," Hayes says. Hayes instead went forward with money he had obtained from Berkeley and the National Science Foundation. He repeated the Xenopus experiment two times, and in April 2002 he published his findings in the Proceedings of the National Academy of Sciences.

He also performed a series of similar experiments using a common native species, the northern leopard frog. Hayes found that doses of atrazine as low as .1 ppb again caused various degrees of "sex reversal" in about a third of the males, and that some of the animals also displayed a freakish abnormality that Hayes had not seen in Xenopus: eggs forming in their testes. In the summer of 2001, Hayes and his students conducted field surveys of wild leopard frogs at eight locations in the United States and found the same deformities they had seen in the lab. At a site on the North Platte River in eastern Wyoming, far from the nearest farmland, Hayes discovered high levels of atrazine in the water and gonad problems in 92 percent of the male leopard frogs. In October 2002 he published these findings in Nature. The following summer he returned to the North Platte and found the atrazine contamination much reduced and only 8 percent of the frogs abnormal. A year later he measured no atrazine in the water at the site, and all the frogs were normal. (Hayes believes that the river had been temporarily contaminated somewhere upstream.)

In his published articles, Hayes argued that atrazine activates a gene that produces an enzyme called aromatase, which converts testosterone to estradiol, the strongest of the naturally occurring estrogens. Elevated levels of aromatase, he proposed, could explain the males' stunted voice boxes and multiple, mismatched sex organs--as well as the fact that atrazine appeared to have no effect on the females. Hayes called the process "chemical castration and feminization." He was not surprised that the abnormalities he found were associated with extremely weak doses of atrazine; hormones, including testosterone and estradiol, typically function at very low concentrations. "If you're a toxicologist, this is a low-dose effect," Hayes says. "If you're an endocrinologist, it's a reasonable effect."

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Chemical poisons tend to be more toxic as the dose increases the classic "linear" dose-response association. But chemicals that affect hormonal systems sometimes operate in nonlinear ways: In women, for example, estradiol is necessary to stimulate ovulation, but a large dose of estradiol--the amount contained in the birth control pill---cancels this effect.

The science of endocrine disruption, as chemical interference with hormones has been dubbed, is new and complex. Unlike acute toxins, which can kill an organism outright, endocrine disrupters cause subtle damage, such as reproductive-system abnormalities or conditions that can lead to cancer. Effects seen at very low doses but that do not occur at higher doses con found traditional toxicological assay techniques. In 1996, Congress directed the EPA to include endocrine-disruption studies as part of its safety screening of licensed chemicals, but a decade later the agency is still trying to develop standards for laboratory tests.

According to Bruce Blumberg, an associate professor of developmental and cell biology at the University of California, Irvine, scientists who study endocrine disruption often see dramatic biological effects when they expose cell cultures to weak chemical concentrations. Curiously, Blumberg says, research sponsored by chemical companies rarely detects such effects.

Atrazine is among the world's oldest and most effective herbicides--the aspirin of weed-killers. It was developed during a period of intense innovation in the chemical industry that began with the Second World War and the invention of 2,4-D, the first "selective" herbicide: it could kill weeds without killing the crops. (It was later mixed with 2,4,5-T by the military to make the decidedly nonselective defoliant Agent Orange.) Syngenta, a company with roots dating back a couple of centuries that also gave the world DDT and LSD, introduced atrazine to the market in 1959. The new chemical was far more selective than 2,4-D--it is nearly impossible to kill corn with the stuff--and it was an immediate hit with farmers. Syngenta does not divulge sales figures for individual products, but atrazine continues to contribute a significant portion of the company's U.S. revenues from selective herbicides, which last year totaled $1.9 billion worldwide.

Atrazine residues are not found in significant amounts in food. Nor is it especially poisonous to vertebrates; it's unlikely that you could dissolve enough atrazine in water to kill a frog. A handful of studies have linked atrazine exposure to increased incidences of cancer in humans, but many more studies have found no evidence of such a correlation. Hayes, for his part, believes that atrazine, because it may cause endocrine problems in people, could play an indirect role in cancer. Estrogen, he points out, is known to promote tumor growth; a current treatment for breast cancer involves a drug that inhibits the production of aromatase. "How can we take the risk of exposing people to something that does the opposite?" he asks. In 2000 the EPA--in a move that downgraded the agency's earlier concerns about atrazine and cancer--declared that the compound is "not likely to be carcinogenic to humans."

Nevertheless, a fraction of the nearly 80 million pounds of atrazine applied to crops in the United States every year ends up contaminating surface water, groundwater, rain, and even fog. In the spring, concentrations in rivers and streams in the Midwest frequently exceed 10 ppb, and Syngenta has twice

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voluntarily reduced the suggested application rate for atrazine on corn, from four pounds per acre to three in 1990, and to two and a half in 1992. Although atrazine breaks down fairly quickly in, soil and shallow surface water, it is more stable in larger bodies of water and in underground aquifers. In 1999 and 2000 the EPA and the United States Geological Survey, measuring reservoirs in agricultural areas of a dozen states, found atrazine in posttreatment drinking-water samples collected from community water systems, in some cases at concentrations of more than 2 ppb. In 2003 the EPA reported that a survey of more than 14,000 water utilities, drawing water from wells in twenty-one states, had found that atrazine, where it previously had been detected, averaged about .55 ppb--more than five times the amount that caused abnormalities in Hayes's initial experiment. Because water can take years to percolate down into aquifers, atrazine would still be found in well water for decades even if use of the pesticide were halted today. That very concern led the European Union to ban atrazine in the fall of 2003.

People, unlike frogs, don't undergo critical developmental stages exposed to the elements, and frogs may be particularly sensitive to waterborne chemicals. Still, in the same year atrazine was banned in the European Union, an American epidemiologist named Shanna Swan, then at the University of Missouri School of Medicine, published research showing reduced semen quality in men exposed to pesticides. Swan compared men in Columbia, Missouri, with men living in Minneapolis. The Columbia group had about half as many moving sperm in their semen as their Minneapolis counterparts. Urine samples from the Columbia group showed significantly higher herbicide residues. Swan says few of the men in Columbia were farmers and that she suspects their exposure to pesticides was through drinking water contamination. Reduced semen quality is correlated not only with reduced fertility but also with testicular cancer. One of the pesticides Swan detected in the Missouri group was atrazine.

On April 16, 2002, the day Hayes's Xenopus study appeared in print, The Wall Street Journal published a brief article about it, in which Tim Pastoor, Syngenta's North American head of research for human safety health issues, described Hayes's findings as "inconclusive." Syngenta, the Journal reported, "considers the Hayes study to be 'preliminary work' that might have to be retracted as the result of more detailed testing." Two months later, Hayes's former colleagues on Syngenta's atrazine research panel issued a press release stating that two teams of scientists, working independently, had tried to replicate Hayes's results and failed. Both studies had been funded by Syngenta and were led by members of the atrazine research panel. One was overseen by James Carr, a biologist at Texas Tech University; the other by John Giesy, a zoologist at Michigan State University. Hayes was furious. "Saying they couldn't replicate my work is different from saying they didn't replicate it," he says.

Reproducibility is a hallmark of good science, and the charge that a researcher's work cannot be duplicated is serious. An experiment that can't be repeated implies either incompetence or fraud on the part of the original author. A perfectly replicated experiment should always yield the same result, in the same way that two identical columns of numbers will add up to the same total. In practice, many variables come into play and experiments are never exactly the same. But as became clear from the data and descriptions of their experiments later submitted to the EPA, both Carr and Giesy departed from Hayes's methods--and neither proved as skillful at the difficult task of rearing frogs. Giesy performed two key

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experiments loosely modeled on Hayes's. In one of the experiments, more than three quarters of the frogs died. In both, the control tanks were accidentally contaminated with atrazine at concentrations averaging at least .1 ppb, rendering the results inconclusive. (Giesy says his experiments were no more contaminated than anyone else's and that he merely had reported the control levels more precisely.)

Carr had problems, too. His frogs had been overcrowded and underfed, and many of his tadpoles failed to achieve metamorphosis. Some that did took longer than usual to reach that stage. Carr did not test atrazine at concentrations of less than 1 ppb. Even so, his experiment did produce frogs with abnormal gonads, though he found the effect statistically significant only at 25 ppb--250 times the amount that caused abnormalities in Hayes's experiment. Ordinarily, the detection of a similar effect in an experiment that only approximates the original is considered evidence that the effect is "robust." (Carr did not respond to my requests for comment.)

In any case, Hayes's research had already caught the attention of the EPA. In April of 2002, Hayes had been contacted by Tom Steeger, a scientist in the agency's Office of Pesticide Programs, in Washington, who said in an email that it would be "imprudent" of the agency to ignore the "disturbing results" of Hayes's investigation. The following July, Steeger visited Hayes's lab, where the experiments on Xenopus and leopard frogs were under way. After Steeger returned to Washington, he exchanged dozens of emails with Hayes and other scientists on the atrazine panel and at Syngenta in an effort to determine who had gotten what right about frogs and atrazine.

The Environmental Protection Agency regulates pesticides under a law called the Federal Insecticide, Fungicide, and Rodenticide Act. Adopted by Congress in 1947 and extensively amended since, FIFRA is now a book-length set of rules, the most important of which is this: the EPA is supposed to weigh a pesticide's economic benefits against any "unreasonable adverse effects" it may have on the environment or on human health. In 1988, Congress adopted the provision to reregister pesticides that had been licensed before 1984.

The EPA does not actually investigate the economic benefits of any pesticide, nor does it usually conduct its own research on the safety of such compounds. When confronted with evidence that a pesticide has adverse effects, the EPA usually responds with a recommendation that the matter be studied further, and under the peculiar logic of pesticide regulation, it is the manufacturer and not the agency that is responsible for testing chemical products. (The EPA stipulates what kinds of studies are necessary and requires companies to submit raw data in addition to safety conclusions.)

One way to maintain the perception that a pesticide is safe is to take a very long time reviewing information suggesting it is not. The EPA routinely reframes questions about the safety of pesticides in such a way that they remain questions, and evidence of adverse effects usually results in a demand for more study. Pesticide makers are allowed extravagant amounts of time for such follow-up work. And because the companies know the EPA must carefully review every study they submit, pesticide makers can game the system by submitting flawed and inconclusive research. The EPA then judiciously pores over the new data, finds it wanting, and

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asks for something more definitive. The oversight the agency thus exercises can be thought of as a kind of business service. The EPA helps chemical companies understand safety concerns in terms of overhead. The agency refers to pesticide makers as "registrants," a term that makes them sound like guests in a luxury hotel, which in some ways does not seem far from accurate.

The Bush Administration has a deserved reputation for hostility to environmental regulation, but the EPA's process for licensing pesticides has become less stringent over the course of many years, under both Republican and Democratic leaders. According to a knowledgeable former EPA official, the agency was more aggressive in restricting and banning pesticides in its early years. It remained more independent and "professional" under the first President Bush than it has since become. During the Clinton years, the former official said, the agency adopted a conciliatory attitude toward pesticide manufacturers in an effort to counter the perception that it was staffed by environmental zealots. At the same time, chemical companies were becoming more adept at forging alliances with farm advocacy groups, which have enormous clout in Washington and have learned how to turn the EPA's "data addiction" to their advantage. "Scientists culturally cannot say no to data," the former official said of the staff in the agency's pesticide program. "It's hard for them to make a decision about what's in front of them when there is a promise of more information in the future." Delay, of course, has decided economic benefits for pesticide makers.

Syngenta's crop-protection division, where Tim Pastoor works, is located in Greensboro, North Carolina, in a leafy, campus-like complex just off Interstate 40. Pastoor, a pleasant, sandy-haired toxicologist, says the regulatory onus on his company is immense--a research program without end. Hearing that work disparaged because it's funded by the company "drives me crazy," Pastoor says. "It's as if they"--the company's safety studies--"are tainted when they're not." In an effort to anticipate the kinds of studies the EPA is likely to request of them, companies like Syngenta often undertake expensive research independent of the regulatory review process. When the company decided to look at atrazine's effects on frogs, it was under no obligation to do so. Pastoor says that since the reregistration process began, in 1994, Syngenta has spent $30 million on atrazine research and submitted close to 200 studies to the EPA. "I can assure you that I'm not concerned about the safety of atrazine use," Pastoor says.

Atrazine is one of nearly 900 pesticides that the EPA identified for reregistration eighteen years ago. In 1994, when the compound was still considered a cancer risk, it was placed under "special review." Twelve years later, with the August deadline for a final decision on reregistration approaching and the special review set to be completed within a year, the EPA's file on atrazine has swollen to more than a million pages of documents. The pace of reevaluation might have been even slower had it not been for a series of deadlines imposed on the EPA by a court order stemming from a case brought against the agency in 1999 by the Natural Resources Defense Council.

The NRDC, a well-funded environmental advocacy group based in Washington, D.C., is frequently in court against the EPA. With respect to atrazine, the group has sued the EPA for violating provisions of FIFRA, the Endangered Species Act, the Food Quality Protection Act, and the Federal Advisory Committee Act. These are not tort cases: the NRDC has sued not for damages on its own behalf or anyone else's

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but instead solely in an attempt to make the EPA follow the federal laws that govern its regulation of pesticides. Like the reregistration process itself, these court cases tend to drag on for years.

Aaron Colangelo, a slight and plainspoken thirty-one-year-old graduate of Harvard Law School and a principal litigator for the NRDC, says that the agency should have suspended atrazine in the spring of 2002, after Hayes published his first article. "There was certainly enough justification to do it," Colangelo says. In atrazine cases, he says, he has often found himself alone at the plaintiffs table across the aisle from attorneys for the EPA and Syngenta--despite the fact that the NRDC has never named the company as a defendant in any of its actions. The EPA apparently is not embarrassed to be joined in court by lawyers for a company that it is supposed to be regulating.

The NRDC has not been alone in urging the EPA to act against atrazine. In 2002 the attorneys general of New York and Connecticut asked the agency to ban atrazine. Judith Schreiber, chief scientist at the Environmental Protection Bureau in the New York Attorney General's Office, wrote a pointed letter to the EPA arguing that the agency's own review of atrazine risks for human health and the environment warranted cancellation of the pesticide. And she scolded the agency for ignoring Hayes's findings. The EPA had failed "to adequately consider the endocrine disruption and reproductive effects of atrazine," Schreiber wrote, adding that Hayes's aromatase theory suggested that atrazine could act through a "common mechanism among frogs, reptiles and mammals, including humans."

In the summer of 2002, Everett Wilson, chief of the U.S. Fish and Wildlife Service's Division of Environmental Quality, also complained to the EPA about atrazine. In a letter to the agency's chemical review manager, Wilson contended that atrazine could harm endangered species, especially amphibians, by interfering with their hormonal processes or by killing the aquatic plants and invertebrates that amphibians eat. Wilson cited the Barton Springs salamander, an endangered amphibian that is known to live only in a springfed pool in a park in downtown Austin, Texas. Water samples collected in Austin by the U.S. Geological Survey show that when it rains, atrazine from grass treatment contaminates the salamander's habitat in concentrations that are sometimes greater than .5 ppb. Unlike FIFRA, the Endangered Species Act, which was adopted by Congress in 1973, contains no provision for balancing adverse environmental outcomes against economic considerations; it simply prohibits harm to any of the more than 1,000 species on the endangered list.

In November 2002, Hayes proposed an experiment he believed could end debate over his findings: he offered to provide Xenopus specimens to three labs in order to run concurrent studies, one by him at Berkeley, one at a lab chosen by Syngenta, and the third at a lab selected by the EPA. Hayes said that he would train lab workers at all locations in protocols--including how to feed and care for the animals--at his own expense. At the experiments' conclusion, each lab would exchange a third of its animals with each of the other labs, allowing all three parties to examine one another's frogs for abnormalities.

The EPA and Syngenta declined Hayes's invitation to collaborate. Jim Carr said in an email that he was "in principle" not opposed to the idea, but complained that Hayes was insensitive to the fact that there were features of his experiment that

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"we do not wish to repeat." Keith Solomon agreed, reminding his colleagues by email of their previous inability to raise frogs using Hayes's methods.

Hayes says that, even allowing for start-up time, these new experiments could have been completed in a matter of months. Instead, the EPA asked for further analysis of the extant data, in the form of white paper that would consider seventeen recent studies--published and unpublished--involving atrazine and amphibians, including research by Hayes, Carr, and Giesy. (Twelve of the projects had been sponsored by Syngenta.) This white paper would, in turn, be submitted to the EPA's Scientific Advisory Panel, a group of seven scientists whose job is to provide the agency with "independent, external, expert scientific peer review." In this case, the panel was to be expanded to fifteen scientists, and a public hearing--a standard feature of such reviews--was scheduled for June 2003.

The white paper--written by Tom Steeger with help from Joe Tietge, a biologist at the EPA's Mid-Continent Ecology Division, in Duluth, Minnesota, who had led the agency's investigation of deformed-frog incidents several years earlier--was never conceived as a means of deciding the safety of atrazine. It was, according to the EPA, an effort to determine "whether there is a need for additional data to characterize more fully atrazine's potential risk to amphibian species, and, if so, what data should be developed." In other words, the white paper was intended from the outset primarily to help the agency decide what further research should be done on atrazine. Hayes deduced as much, and complained to Steeger that the white paper would merely lead to a routine call for more study--and that inclusion of Syngenta's dubious research was an effort to "dilute" his own legitimate findings with "garbage."

Extraordinary attention was paid to the white paper's wording. In May 2003 it was reviewed by two departments at the White House, the Council on Environmental Quality and the Office of Management and Budget, both of which advise the president on environmental policy. According to the NRDC's Aaron Colangelo, this degree of executive-branch involvement in the oversight of a single pesticide registration was unprecedented.

On June 17, 2003, the Scientific Advisory Panel convened for a four-day public hearing at the Crowne Plaza Hotel in the shimmery Crystal City suburb of Washington, D.C. Unlike peer reviewers for scholarly journals, who are unpaid and free to make whatever comments they like about the research they are asked to evaluate, the advisory panel members worked within narrow guidelines in assessing the white paper. They were paid $400 a day, and, although panelists sign detailed financial-disclosure forms crafted to expose conflicts of interest, there is no prohibition against scientists serving on the panel who receive research funding from the EPA in other areas and who thus might be reluctant to criticize its findings.

In their assessment, Steeger and Tietge wrote that there was enough evidence to "establish the plausibility of a hypothesis that atrazine could affect amphibian development," but, because of flaws in all of the existing studies, the EPA could neither accept nor reject such a theory. They proposed that Syngenta conduct further research. In its report to the EPA, submitted in August 2003, the Scientific Advisory Panel agreed that more research was needed in order to understand the effects of atrazine on frog development. The panel added that the

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existing data was sufficient to "warrant concern"--a conclusion only marginally more forceful than the white paper's ambiguous finding.

"I would never go on an EPA panel again," says Darcy Kelley, a biology professor at Columbia University who participated in the panel's deliberation, and who is a leading authority on sexual differentiation in Xenopus. "It's a curious process, which is run within a set of guidelines that guarantee nothing will be done." Kelley, who has visited the EPA's lab in Duluth, said she was puzzled that the agency hadn't tried to replicate Hayes's experiment and surprised that each of the seventeen studies was given equal weight in the EPA's evaluation. She found Hayes's research worrisome because hermaphroditism does not normally occur in Xenopus. "He had the most striking results I've seen in a long time," she said. "I'd have said if you want to err on the side of caution, then you should not re-license atrazine." But, as David Skelly, an ecologist at Yale University who was also on the panel, put it, the group was not permitted to reach such a "novel conclusion." Still, in its report, the panel noted that, with the exception of the two experiments by John Giesy at Michigan State, the laboratory studies all suggested that atrazine disrupts normal reproductive development in frogs. "The inability to detect gonadal abnormalities with atrazine exposure in (Giesy's experiments) should not detract from the positive results noted in the majority of the studies," the panel members wrote.

In the fall of 2003, the EPA concluded an interim reregistration of atrazine. In compliance with the recommendation of the advisory panel, the agency also ordered Syngenta to conduct additional experiments on frogs and atrazine. Two years later, in the summer of 2005, scientists at Syngenta began their initial testing of atrazine on Xenopus. They expect to have results by the end of this year, more than four years after Tyrone Hayes proposed the joint experiment that could have resolved the issue in a few months. Meanwhile, in all likelihood, the reregistration of atrazine will be finalized this August.

In January, Hayes published two new papers in Environmental Health Perspectives. In one paper, he showed that when frogs are exposed to atrazine in combination with other pesticides--as they are in the environment--the damage to the animals' hormonal systems is more severe than from exposure to atrazine alone. In the other, he reported that when male tadpoles are exposed to estradiol (or to a synthetic compound that suppresses testosterone) they develop the same kinds of gonadal abnormalities that are associated with atrazine--a finding, he argues, that provides further support for his theory of "chemical castration and feminization." Hayes has also been trying to figure out why some male frogs in his experiments fail to exhibit elevated levels of aromatase or gonadal abnormalities after being exposed to atrazine. (The reason, he thinks, may have something to do with natural differences in the rates at which the frogs develop.)

Although Syngenta's current research is not, strictly speaking, an attempt to replicate Hayes's work--the experiments involve alternative methods--Hayes says he has full confidence that they will find the same adverse effect. Different methods and different strains of Xenopus could result in somewhat different frequencies and patterns of abnormal gonadal development or even no deformities at all. But, Hayes says, he can think of no reason why the essential result would not be the same. He also knows of no reason why the EPA will not continue to do nothing as the testing moves on to another phase. "My view is that the EPA is never going to

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take action on atrazine," Hayes says.

Legally, the EPA needn't find a threat to human health to ban atrazine. Adverse effects in the environment are sufficient for the agency to take action, and in the view of many biologists it makes little sense to see humans in isolation from the environment. The question of what direct effects, if any, atrazine has on human health will be hard to answer, and will likely depend on inferences drawn from studies of surrogate species. Such inferences are never certain. Vertebrate toxicology is a kind of Russian roulette: Some species get lucky when they're exposed to chemicals; some don't. Thalidomide--the sedative that caused horrific birth defects in human infants in forty-six countries half a century ago--was believed safe because tests showed it had no effect on rats. In the very same ecosystems where Tyrone Hayes has found abnormal northern leopard frogs, he has also discovered that a close relative of that species--the plains leopard frog--appears to be unaffected by atrazine. As is usually the case with environmental contaminants, the real-world experiment is already up and running.

William Souder is the author of A Plague of Frogs and, most recently, Under a Wild Sky: John James Audubon and the Making of The Birds of America, which was a finalist for the 2005 Pulitzer Prize in biography.

---- INDEX REFERENCES ----

COMPANY: CROWNE PLAZA HOTEL; SYNGENTA AG; NOVARTIS AG

NEWS SUBJECT: (Economics & Trade (1EC26))

INDUSTRY: (Animal Research & Animal Rights (1AN65); Bioethics (1BI56); Environmental (1EN24); Agriculture, Food & Beverage Regulatory (1AG56); Chemistry (1CH57); Agrochemicals (1AG08); Chemicals (1CH04); Environmental Regulatory (1EN91); Manufacturing (1MA74); Science (1SC89); Science & Engineering (1SC33); Healthcare (1HE06); Healthcare Policy (1HE46); Physical Science (1PH15); Nature & Wildlife (1NA75); Agriculture (1AG63); Pesticides (1PE12); Agriculture, Food & Beverage (1AG53))

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Delay; Democratic; Ecology Division; Everett Wilson; Giesy; Hayes; Irvine; James Audubon; James Carr; Jim Carr; John Giesy; Judith Schreiber; Keith Solomon; Kelley; Legally; Newly; Ordinarily; Pastoor; Purina Rabbit Chow; Reproducibility; Schreiber; Scientists; Shanna Swan; Steeger; Swan; Syngenta; Thalidomide; Tim Pastoor; Tom Steeger; Twelve; Tyrone; Tyrone Hayes; Urine; William Souder; Wilson; Xenopus) (University of California (Officials and employees); Atrazine (Complications and side effects); Atrazine (Research); Frogs (Research); Frogs (Physiological aspects); Frogs (Statistics); Herbicides (Complications and side effects); Herbicides (Research)) (Science & research (310); Labor Distribution by Employer (680); Executive changes & profiles (540)) (California (1U9CA))

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ATTACHMENT 18

Playing Chicken with Antibiotics:
Previously Undisclosed FDA Documents Show Antibiotic Feed Additives Don't Meet the Agency's Own Safety Standards

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SUMMARY

Between 2001 and 2010, the United States Food and Drug Administration (FDA) quietly reviewed the safety of 30 penicillin and tetracycline antibiotic[i] feed additives[ii] approved for "nontherapeutic use" in livestock and poultry.[iii] Nontherapeutic use refers to using antibiotics for growth promotion or to prevent disease in typically crowded, often unsanitary conditions.[1] NRDC obtained the previously undisclosed review documents from the FDA as a result of a Freedom of Information Act (FOIA) request to the agency and subsequent litigation made necessary by FDA's failure to provide any of the requested documents.

FDA's scientific reviewers' findings show that *none* of these products would likely be approvable as new additives for nontherapeutic livestock use if submitted today, under current FDA guidelines. Eighteen of the 30 reviewed feed additives were deemed to pose a "high risk" of exposing humans to antibiotic-resistant bacteria through the food supply, based on the information available. The remainder lacked adequate data for the reviewers to make any determination and their safety remains unproven. In addition, FDA concluded in their review that at least 26 of the reviewed feed additives do not satisfy even the safety standards set by FDA in 1973.

To our knowledge, FDA has taken no action since the reviews to revoke approvals for any of these antibiotic feed additives (although two were voluntarily withdrawn by the drug manufacturer). The FDA does not disclose sales of specific animal drug products, and we have no information about the quantities of these specific antibiotic additives that were sold for livestock use or administered to food animals. However, we found evidence suggesting that at least nine of these additives are being marketed today, and all but the two voluntarily withdrawn additives remain approved for use today.

The significance of these findings extends far beyond the 30 antibiotic feed additives reviewed. FDA data indicate that the types of antibiotics in the reviewed additives—tetracyclines and penicillins—together make up nearly half of all the antibiotics used in animal agriculture. Other feed additives with these same antibiotics, including generics, that are approved for similar uses would likely pose a similar risk of promoting antibiotic resistance. This risk was recognized by FDA in 1977 when it proposed to withdraw approvals for animal feed additives containing penicillin and most tetracyclines.[2]

Furthermore, the use of tetracyclines and penicillins in animal feed is part of a larger problem of antibiotic overuse. Approximately 70 percent of all sales of medically important antibiotics in the United States are for livestock use.[3] Scientists have demonstrated that nontherapeutic use of antibiotics to raise livestock promotes drug-resistant bacteria that can migrate from livestock facilities and threaten public health. These bacteria can spread resistant traits to other bacteria, and some of these shared traits also can confer resistance to antibiotics used primarily in human medicine.[4]

Unfortunately, the FDA's failure to act on its own findings about the 30 reviewed antibiotic feed additives is part of a larger pattern of delay and inaction in tackling livestock drug use that goes back four decades. A recent voluntary policy adopted by FDA, "Guidance #213," recognizes the problem, but lacks meaningful requirements and seems unlikely to curb uses of the antibiotics reviewed here or any of the other problematic uses (for a number of reasons discussed further below). It is time for decisive action to help protect the public from the threat of antibiotic resistance. The FDA should:

1. Complete the decades-delayed process for withdrawing approval of penicillin and tetracyclines in animal feed, strictly limiting their use to treating sick animals and, in rare circumstances, to controlling disease outbreaks.
2. Initiate the process for withdrawing approval for all other classes of medically important antibiotics approved for nontherapeutic livestock use that are not shown to be safe.

In the face of the FDA's continued inaction, Congress, food industry leaders, and consumers should step in to demand change. Congress should insist on real regulation of livestock antibiotic use as outlined in the Preservation of Antibiotics for Medical Treatment Act (PAMTA) in the House of Representatives[5] and the Preventing Antibiotic Resistance Act (PARA) in the Senate.[6] In the meantime, large food companies and consumers can reduce livestock antibiotic use by choosing meat and poultry supplied by producers that promote antibiotic stewardship in the livestock and poultry industry.

i Here we use "antibiotic" to refer to all antibacterial agents, including both synthetic antibacterials and those produced from a natural source. For convenience, and based on common usage, we use "antibiotic" throughout.

ii For convenience, "antibiotic feed additives" refers throughout to drug products added to both feed and water.

iii Hereafter, for ease of use, "livestock and poultry" is referred to only as "livestock." Similarly, "livestock facilities" refers to both livestock and poultry facilities.

A BRIEF OVERVIEW OF ANTIBIOTICS, RESISTANCE, AND LIVESTOCK USE

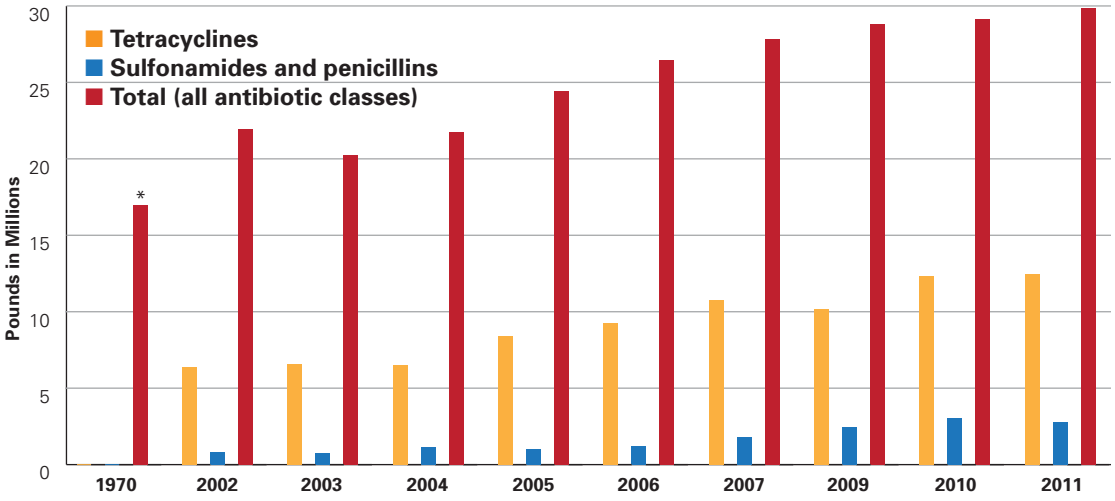
Antibiotics are the miracle drugs of the past century; they transformed medical care by turning infections that often proved fatal or required amputation into easy-to-treat illnesses.[7] Yet overuse and misuse of these medicines in both humans and food animals is causing rising rates of antibiotic resistance. The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) have repeatedly highlighted the risk of an impending post-antibiotic era due to growing resistance and have called for action, including the curtailment of inappropriate uses in livestock.[8]

In a report on Antibiotic Resistance Threats in the United States, 2013, the CDC says that "[i]n most cases, antibiotic-resistant infections require prolonged and/or costlier treatments, extend hospital stays, necessitate additional doctor visits and healthcare use, and result in greater disability and death compared with infections that are easily treatable with antibiotics."[9] The agency also warns that declining effectiveness of antibiotics will undermine "many life-saving and life-improving" procedures and treatments, such as "joint replacements, organ transplants, cancer therapy, and treatment of chronic diseases such as diabetes, asthma, [and] rheumatoid arthritis."[10]

As U.S. production of meat and poultry products has grown, U.S. livestock farms have become larger, leading to more confinement and crowding and also to greater risk of disease among the animals.[11] After the FDA approved the use of antibiotics in livestock feed in 1951, producers began relying on nontherapeutic use of antibiotics to speed animal growth and to prevent disease.[12] Studies by both livestock scientists and advocacy groups, while they have data gaps, suggest that the majority of all antibiotic use in U.S. livestock is for these nontherapeutic purposes, rather than for the treatment of sick animals.[13]

Using antibiotics at low doses for extended periods of time in crowded livestock facilities can lead to more drug-resistant bacteria that can outcompete other bacteria, and escape livestock facilities to threaten human health.[14] A large chorus of scientists, health experts, and government agencies warns that the overuse and misuse of antibiotics in livestock production is contributing to the expanding public health crisis of antibiotic resistance, depleting the physician's arsenal of antibiotics effective for treating infections in people. In its recent report, CDC notes that "much of antibiotic use in animals is unnecessary and inappropriate and makes everyone less safe"[15] and emphasizes that antibiotic overuse in both human medicine and livestock production is contributing to the problem of resistance.[16] The report notes that antibiotic resistance is associated with at least 2 million illnesses and 23,000 deaths each year[17] and shows that as newer antibiotics become less effective, older antibiotics may matter more.[18]

Figure 1: Estimated use of tetracyclines and penicillins/sulfonamides from 1970 to 2011 in livestock production.



Numbers for 1970 and 2002-2011 are based on estimates from the FDA and quantities sold domestically as reported by AHI and to the FDA. Penicillin and sulfonamides were reported together.

* No estimate of penicillin and tetracycline use is available for 1970.

(Total=all antibiotic classes.)

Source: Data for graph compiled from several sources. Animal Health Institute, http://www.ahi.org/archives/2008/11/2007-antibiotics-sales/; The Poultry Site, http://www.thepoultrysite.com/poultrynews/7985/antibiotic-use-in-us-animals-rises-in-2004; Food and Drug Administration "Summary Report on Antimicrobial Sold for Food Producing Animals-2009," http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM231851.pdf; Food and Drug Administration, "Summary Report on Antimicrobial Sold for Food Producing Animals-2010," http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm277657.pdf; Food and Drug Administration, "Summary Report on Antimicrobial Sold for Food Producing Animals-2011," http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf; Food and Drug Administration, "Statement of Gregory J. Ahart, Director, Human Resources Division before the House Committee on Interstate and Foreign Commerce on Food and Drug Administration's Regulation of Antibiotics Used in Animal Feeds," http://www.gao.gov/assets/100/98536.pdf

PENICILLINS AND TETRACYCLINES: USE IN ANIMAL FEED AND FOR HUMAN HEALTH

The reviewed antibiotic additives—penicillins and tetracyclines—are also important for treating human disease. In the U.S. in 2011, penicillins accounted for 44 percent of the total antibiotics sold for human medicine, and tetracyclines accounted for 3.5 percent.[19] The World Health Organization lists penicillins as critically important for human medicine and lists tetracyclines as highly important.[20] The FDA itself recognizes both as highly important, even under its limited criteria whereby antibiotics are designated "critically important" only if the drugs are used to treat gut pathogens that cause foodborne illness.[21] A partial listing of continuing medical uses of these drugs is provided in Table 1, below.[22] Unfortunately, penicillins and tetracyclines are no longer effective in fighting some infections because of increased resistance, decreasing options for treatment.[23]

Table 1: Overview of common medical conditions treated with penicillins and tetracyclines

Antibiotic Class	Antibiotic	Common Uses in Human Medicine[24]
Penicillins	Penicillin G	Syphilis Bacterial meningitis
	Ampicillin	Bacterial meningitis Leptospirosis Complicated UTI (kidney complication)
Tetracyclines	Tetracycline	Eye infection Early stages of syphilis Ehrlichiosis (spread by ticks and fleas)
	Doxycycline*	Chlamydia Gonorrhea Bronchitis Tularemia Lyme Disease

*Specific antibiotic not used in livestock, but cross resistance between antibiotic used in livestock and this antibiotic has been observed.[25]

At the same time, tetracyclines and penicillins are among the most commonly used antibiotics in livestock production in the U.S. In 2011, 42 percent of antibiotics used in animals were tetracyclines and 6.5 percent were penicillins (Figure 1).[26]

ANTIBIOTIC-RESISTANT BACTERIA CAN ESCAPE LIVESTOCK FACILITIES TO THREATEN PUBLIC HEALTH

A rich body of scientific literature, reinforced by the latest CDC report on emerging antibiotic resistance, shows that antibiotic-resistant bacteria bred in livestock facilities can make their way off the farm in a number of ways. People who work with livestock or in meat production/processing can carry the resistant bacteria into their communities.[27] Resistant bacteria can travel from the farm in air or water, can wind up in the soil when manure is applied to crops, which in turn can end up on fruits and vegetables, and can be found in meat on retail shelves.[28] Even insects and rats can carry antibiotic-resistant bacteria from farms to surrounding communities.[29] There is mounting evidence that antibiotic-resistant bacteria that originate in livestock are reaching our communities and homes.[30]

Researchers have also demonstrated that the overuse and misuse of one antibiotic can actually lead to bacterial resistance to other antibiotics. This means that nontherapeutic use of penicillins and tetracyclines in animal feed can compromise the effectiveness of other medically important antibiotics that were not used in livestock facilities.[31] This occurs through mechanisms described by scientists as "cross resistance" or "co-resistance."[32] (See box on antibiotic resistance).

Antibiotic resistance: How antibiotic use increases the population of resistant bacteria

Mutation and multiplication

Bacteria multiply rapidly. Each time this happens, there is a small chance that a gene in a bacterium will mutate in a way that makes it resistant to a particular antibiotic.

While new resistance genes can and do arise, bacterial resistance and associated genes have long existed, although usually in very low numbers.[33] Using an antibiotic, for instance, for growth promotion and disease prevention purposes, allows resistant bacteria that can withstand the antibiotic to survive and multiply. This creates many new bacteria that carry the same resistance gene, while bacterial populations susceptible to antibiotics die off, and ultimately increases the overall population of antibiotic-resistant bacteria.[34]

Gene sharing and multiplication

Bacteria that are resistant to antibiotics can, in some cases, pass a resistance gene or 'trait' on to other bacteria, essentially "teaching" them how to endure an antibiotic. One or more resistance genes can be passed from one bacterium to another. This means that a bacterium can become resistant to an antibiotic it was never exposed to. This can even occur between different types of bacteria.[35] This gene-sharing can occur in any environment, including on the farm; in air, water, and soil; and in the community, including in the animal and human gut.[36]

Cross resistance: A resistance trait that confers resistance to multiple antibiotics

Sometimes a bacterium's ability to resist one antibiotic enables it to resist other antibiotics as well, even those it was not exposed to. In simple terms, a bacterium can figure out, and/or share with a neighbor, a way to fend off antibiotics that are similar in structure or mechanism. Resistance to drugs both within a class of antibiotics or across multiple classes of antibiotics can be shared in this way. For example, as indicated in Table 1, bacteria that are resistant to oxytetracycline can also be resistant to Doxycycline, another tetracycline used only in human medicine.[37]

Resistance traits that are shared can also confer resistance to drugs across antibiotic classes. A prime example of such a trait is the presence of antibiotic "pumps" in the bacteria. These literally pump out antibiotics from bacterial cells, and thereby make bacteria resistant.[38] Some of these pumps are very versatile and can pump out practically all classes of antibiotics currently used in medicine.[39] When this trait is transferred from one bacterium to another, the recipient bacterium can now withstand any antibiotic that the pump works on.

Co-resistance: Clusters of resistance traits that confer multidrug resistance

The ability of bacteria to move around and share genes also enables them to accumulate a cluster of resistant genes or traits in a single transferrable unit.[40] In one extreme case, ten resistance genes to eight different classes of antibiotics were found in such a unit.[41] This can lead to an increase in multidrug resistance in the population when even one of these antibiotics is used, resulting in the selection of bacteria that have received the cluster from their neighbors. For years the USDA, FDA, and CDC have been testing for several known clusters of resistant genes, such as the resistance (and transferable) unit ACSSuT (resistance to ampicillin, chloramphenicol, streptomycin, sulfonamides, and tetracycline), and such clusters are often detected.[42] The problem of co-resistant bacteria is well known in both livestock production and human medicine.

MAIN FINDINGS OF THE FDA REVIEW

NRDC obtained copies of the FDA review documents following litigation over a Freedom of Information Act (FOIA) request.[43] The documents tell a story of FDA's continuing inaction on antibiotic use in livestock even after the agency's own re-examination of 30 livestock antibiotic feed additives, some of which have been allowed for livestock use since the 1950s,[44] showed that these approved antibiotics have not been shown to be safe.[45] (For further details on the documents, see Appendix.) Starting in 2001 and concluding in 2010, FDA scientists, with expertise in fields such as veterinary medicine and microbiology, reviewed livestock antibiotic feed additives containing penicillin and/or tetracyclines.[46] The review was triggered by legislation in 2001 that set aside money for the FDA to work on antibiotics,[47] and was discontinued in 2010 for unknown reasons.[48]

The FDA scientists reviewed the livestock feed additives, listed by NADA (New Animal Drug Application) number in Appendix I, according to two sets of criteria: safety regulations adopted by FDA in 1973 and FDA's 2003 guidelines for evaluating the safety of new animal antibiotic drugs (see sidebar).

The findings of the FDA review are troubling. Of the 30 reviewed antibiotic feed additives, 26 have never met the safety criteria established by FDA in 1973.[49] The 1973 safety requirements mandated that drug manufacturers submit scientific studies that addressed several criteria, including evidence that establishes that the nontherapeutic use of the antibiotics in animal feed did not promote resistance to antibiotics used in human medicine (see sidebar).[50] In addition to the 26, three other antibiotic additives were found not to have met the 1973 safety requirements (and thus were not proven to be safe), although the requirements may not have applied.[51] Of the 30 reviewed feed additives, only one was found by FDA (in 1986) to meet the 1973 safety standards; however it was found to have failed the agency's standard for efficacy.[52] It too remains approved for use.

Furthermore, when these previously approved antibiotic feed additives were evaluated against the FDA's 2003 antimicrobial safety guidelines (Guidance #152) for the evaluation of a new animal drug,[53] the agency found that 18 of the 30 antibiotic feed additives posed a high risk of exposing humans to antibiotic-resistant bacteria through the food chain. While FDA did not have sufficient data to conduct a comprehensive risk assessment for any of the 30 additives, it did have enough information to conduct an abbreviated risk assessment for these 18 additives, which varied in the level of detail in the assessment. In all of these cases, FDA concluded that, based on the information available, these were "high risk" uses. For the remaining 12 additives, the drug manufacturers had not provided sufficient evidence for FDA to even determine the level of risk for human health posed by the additives, let alone to determine that the additives are safe as used (see Figure 1). Thus, none of the 30 reviewed feed additives could likely be approved in their current forms today.

Guidance #152 calls for the characterization of safety through the assessment of hazard (or level of risk) before approval of all new animal drugs. This allows the FDA to set the right restrictions for use of the drug in order to manage risk: under Guidance #152, high-risk drugs could only be approved for treatment of individual animals for short periods of time (less than 21 days).[54] Yet, the existing approvals for these 18 "high-risk" feed additives would allow much wider use. They are approved for over-the-counter use for long periods of time with no restriction on the number of animals to which they are administered. Thus, they could not be approved in their current forms today. The other 12 feed additives could not be approved today unless their safety was established[55] and FDA concluded that it did not even have sufficient information to estimate risk (see Appendix I).

The FDA has not withdrawn approvals for any of the reviewed antibiotic feed additives, even though the agency is required to do so when a drug is not proven to be safe.[56] FDA did send letters to "sponsors" (sponsoring company) in 2004 for six of these antibiotic feed additives deemed "high risk," requesting information to address concerns that the additives might promote antibiotic resistance (see Appendix III). The FDA records do not show that any of the sponsors provided additional studies that addressed the FDA's concerns (see Appendix III). Nor do the documents show that FDA took any further action.[57]

The FDA does not disclose sales of specific animal drug products, and we have no information about the quantities of these specific antibiotic additives that were sold for livestock use or administered to food animals. However, we found evidence suggesting that at least nine of these feed additives are being marketed today (see Appendix II), and all but two apparently voluntarily withdrawn additives remain approved for use today.[58]

FDA's Criteria for Evaluating the Safety of Approved Feed Additives

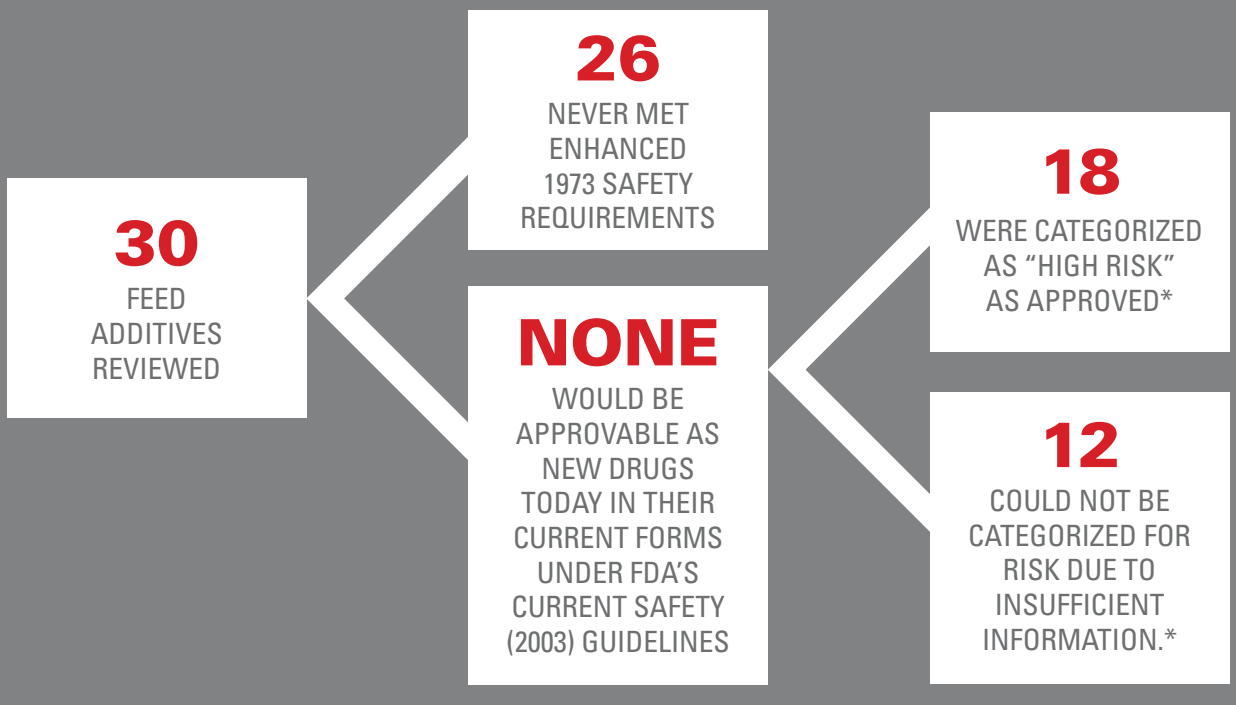
1973 Criteria (21 C.F.R. § 558.15)[59]
Beginning in 1973, the FDA required the submission of data to establish the safety of antibiotic use in animals for nontherapeutic purposes (growth promotion and disease prevention). Required submissions include studies demonstrating that the antibiotics feed additive does not promote resistance to antibiotics used in human medicine or increase *Salmonella* shedding in fecal matter when used in animal feed for growth promotion and disease prevention, as recommended by an FDA task force in 1972.

2003 Criteria (Guidance for Industry #152)[60]
The FDA's 2003 Guidance criteria evaluate antibiotic use on the basis of three parameters:

1. Risk that the antibiotic(s) added to feed will result in the emergence or selection of resistant bacteria in the animal being fed.
2. Likelihood of human exposure to a foodborne bacterium of human health concern.
3. Risk of adverse human health consequences if exposure occurs. This focuses primarily on the importance of the antibiotic class for human medicine and whether its effectiveness might be compromised.

The three factors above are combined to create a risk estimation of high, medium, and low. The criteria then describe allowed conditions of use for each of the different levels of risk such as restrictions on number of animals that can be treated at a time.

FDA Review of Approved Nontherapeutic Antibiotic Animal Feed Additives



* FDA must not approve or must withdraw approval for drugs that are not shown to be safe. [Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b(d)(1)(B), (e)(1)(B).]

Example of FDA Inaction: Antibiotic Feed Additives That Continue to Be Sold Without Being Shown to Be Safe

CASE 1: Pennchlor SP 250/500: An antibiotic feed additive that made it to market without demonstrating safety relating to antimicrobial resistance.

The sponsor proposed but never submitted studies to address the 1973 safety criteria.[61] FDA's review does not mention any other studies that proved safety regarding the risk of antimicrobial resistance.[62] FDA sent a letter to the sponsor in 2004 because it concluded that the feed additive likely posed a "high risk" for promoting resistance in bacteria of human health concern and requested additional safety information.[63] Notably, FDA's letter focused only on growth promotion claims for the feed additive, even though prevention claims were approved for exactly the same kind of use that FDA had found not to have met safety criteria in the growth promotion context.[64,65,66] Both claims were approved with exactly the same restrictions (or lack thereof) on doses, dosage durations, and number of animals that can be treated.[67] There is nothing in the FDA documents that shows that the sponsor provided any new studies that addressed FDA's concerns.[68] FDA does not appear to have taken any action to withdraw approval even for the growth promotion claims it raised in its letter.[69] Today, Pennchlor SP250 continues to be marketed and is used in swine feeds.[70]

CASE 2: Penicillin G Procaine 50/100: An antibiotic feed additive that failed to meet safety criteria and is still marketed today.

In 1997, the FDA asked the sponsor to voluntarily withdraw this antibiotic additive due to increased concern from public officials and members of the health care community regarding the emergence of antimicrobial resistance.[71] In the same letter, the FDA stated that the product failed to meet antimicrobial-resistance safety criteria.[72] In its review, FDA noted increased microbial resistance was observed when the antibiotic feed additive was administered in feed to animals.[73] The sponsor apparently disputed this finding[74], yet the FDA documents do not contain any other studies to address the safety issue.[75] FDA sent another letter to the sponsor in 2004 laying out its concerns about resistance.[76] The record does not show that the sponsor submitted any new studies.[77] FDA never required the sponsor to take the antibiotic feed additive off the market, and it is still sold as a growth promoter in feed.[78]

Summary: Two medically important antibiotics in use in feed additives that have not been proven to be safe

Feed Additive name	Case I: Pennchlor SP 250/ Pennchlor SP 500	Case II: Penicillin G Procaine 50/100
NADA number	138-934	046-666
Antibiotic class in product	Penicillin, tetracycline, sulfonamides	Penicillin
Currently marketed by:	Pennfield Oil Co.[i]	Zoetis, Inc.[ii]
Approved for use in:	Swine	Non-laying chickens, turkeys, pheasants, and quail
Disease treatment and prevention:	Yes	No
Growth promotion:	Yes	Yes

i Pennfield Oil Co. is a large global animal health company. This company is not the original sponsoring company for the antibiotic feed additive.
ii Zoetis, a former business unit of Pfizer, is a large global animal health company. This company is not the original sponsoring company for the antibiotic feed additive.

HISTORY OF FDA INACTION

The failure to follow up on the recent review of antibiotic feed additives containing penicillin and/or tetracyclines is just the latest example of the FDA's inaction in the face of mounting evidence of public health threats stemming from the overuse and misuse of antibiotics in livestock. This inertia goes back four decades. In 1970, the FDA convened a task force of scientists from multiple agencies, including the National Institutes of Health, the U.S. Department of Agriculture, and the CDC, as well as from universities and industry. The task force found that the use of nontherapeutic antibiotics could threaten human health due to the likely rise of antibiotic resistance.[79]

Similar findings in the Swann Report, a 1969 report issued by the British government that inspired the creation of the FDA task force, had spurred Europe into action, leading to the removal of penicillin and tetracycline as growth promoters in animal feed in several European countries.[80] The European Union has since banned the use of all antibiotic growth promoters in animal feed, and Denmark has gone further to disallow prophylactic uses.[81]

Following the findings of the FDA task force, FDA adopted the 1973 regulations requiring drug manufacturers to prove the safety of using antibiotics in animal feed.[82] When drug manufacturers failed to establish safety pursuant to the 1973 regulations, in 1977, the FDA found that the use of penicillin and tetracyclines in animal feed was not shown to be safe and proposed to withdraw approval for those uses.[83] But the agency never followed through to complete the process. In 2012, NRDC sued to force the agency to act and won two court orders, including a directive to begin cancellation proceedings for penicillin and tetracyclines in animal feed.[84] The FDA then appealed. A decision is pending.

In 2003, the agency put out nonbinding guidelines (Guidance #152) that the agency follows in evaluating applications for new approvals of antibiotics for livestock use.[85] The 2003 guidelines were designed to increase the safety of new livestock drugs by reducing the likelihood that they would contribute to the development and spread of antibiotic-resistant bacteria via food. However, the 2003 guidelines do not apply to drugs that were previously approved, i.e., most of the antibiotics being used in livestock today.[86]

Since then, the agency has recently approved more voluntary guidelines (Guidance #213)—non-binding recommendations—to guide the use and marketing of previously approved livestock antibiotics.[87] A critical loophole is that while FDA's proposed guidelines would encourage drug manufacturers to discontinue selling drugs to speed up animal growth ("growth promotion"), it does not discourage the continuation of very similar or even identical uses as long as the intent is to prevent disease ("disease prevention"), even in cases where the animals are not sick and the use is driven by the anticipated effects of crowded and unsanitary conditions often found on livestock facilities. According to the FDA, "disease prevention involves the administration of an antimicrobial drug to animals, none of which are exhibiting clinical signs of disease, in a situation where disease is likely to occur if the drug is not administered."[88] Because many drugs are approved for both growth promotion and disease prevention uses,[89] most current uses can continue under a different label.

Action to Protect Public Health

The FDA should immediately move to end nontherapeutic uses of the reviewed penicillins and tetracyclines and should limit uses of these medicines to treat sick animals or, in rare cases, to control disease outbreaks. The drug manufacturers of these antibiotic feed additives have failed for four decades to prove that they are safe for human health, as they were required to by law.[90] And FDA has failed to withdraw approval for these drugs in that time, in spite of the drug manufacturers' failure to prove the safety of their products.

As described above, the public health risks found by the FDA's review of 30 antibiotic feed additives are an indicator of a larger threat. The nontherapeutic livestock use of other penicillins and tetracyclines—and, indeed, any other medically important antibiotics—poses a risk of breeding resistant bacteria and contributing to the spread of antibiotic resistance. The FDA should therefore move swiftly to take the necessary steps to eliminate all nontherapeutic uses of all classes of medically important antibiotics in livestock production. FDA should also require improved reporting on livestock antibiotics, including reporting by users of these antibiotics, to enable the agency to track progress in meeting this goal.

Congress must act

If the FDA fails to take action, then Congress should step in to ensure that these essential medicines continue to be effective for humans for as long as possible. It should pass the Preventing Antibiotic Resistance Act and the Preservation of Antibiotics for Medical Treatment Act, both of which would phase out the nontherapeutic use of medically important antibiotics in animal feed.

Food companies and consumers should not wait for federal policy reform

While federal policymakers continue to delay, consumers and business leaders can make progress in promoting antibiotic stewardship in the livestock industry. Consumers should purchase animal products labeled "Certified Organic" or "No Antibiotics Administered" when they can. Food companies with large purchasing power should specify antibiotic stewardship requirements for producers who supply them. While many livestock producers have innovative production systems that are not reliant on nontherapeutic antibiotic use, others must now acknowledge the risks of these practices and transition their operations away from antibiotic dependency.

METHODS

EVALUATION OF DOCUMENTS:

Four volumes of the FDA review were received and the volumes included short and long versions of product reviews of penicillin and tetracycline feed additives. The FDA review was carried out from 2001 to 2010 by the Microbial Food Safety Team (HFV 157) in the Office of New Animal Drug Evaluation. Each review (Microbiologist's review) included a brief summary, a review of the administrative record, and conclusions. Specifically, a review of the administrative record included assessment of 21 C.F.R. § 558.15 (1973 safety and efficacy criteria) information, and assessment of the administrative record using Guidance for the Industry (GFI) #152. Extra documentation was provided that pertained to studies addressing 21 CFR 558.15, email correspondence related to the review team, correspondence between the sponsor and the Center for Veterinary Medicine (CVM), as well as background literature and related presentations or posters. Information presented in Appendix I is based on the short and long versions of the product reviews by the Microbial Food Safety Team including summarized 21 CFR 558.15 information, summarized correspondence and conclusions made by the FDA review team.

EVIDENCE OF MARKETING:

NADA numbers were entered into the Animal Drugs @ FDA (database of Approved Animal Drug Products, http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/). The current sponsor was identified and a search was performed for any evidence of current marketing (including product inserts, MSDS sheets, summary information, etc.) In addition, a search was performed using either the NADA number or the proprietary name and evidence of inclusion in any current or recent catalogs was included as evidence. In one case evidence was found of a generic product based on an identified NADA in the FDA review. The Feed Additive Compendium contained names of several products listed in Appendix I. Because NADA numbers are not associated with those products in the Compendium and many products have similar names, results from the Feed Additive Compendium are not included in Appendix II.

EVIDENCE OF WITHDRAWAL:

NADA numbers were entered into the Animal Drugs @ FDA (database of Approved Animal Drug Products, http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/). NADA numbers were cross referenced to the FDA Green Book (Section 6: Voluntary Withdrawals and monthly updates to Jan. 2014, The current status of the drug was assessed and in cases of withdrawal by the sponsor, such a status was noted.

APPENDIX I

Compilation of FDA scientists' review of 30 penicillin and tetracycline feed additives regarding 1973 criteria and Guidance #152.

Name of product	Volume of FDA Review	NADA Number	Met 1973 Safety Criteria	1973 Safety Criteria Citation	Risk Estimation (Guidance 152)	Risk Citation	Additional Information
Terramycin Animal Formula, Soluble Powder	Vol. I	008-622[#ii]	Not met	FDA001732	High risk**[#i]	FDA001739	May not be applicable to 1973 criteria, Animal Drugs @FDA
Terramycin Type A medicated Articles	Vol. I	008-804	Met (in 1986)	FDA002102/ FDA002105/ FDA002110	Not enough information	FDA002114	
Aureomix Granular 500	Vol. II	035-688	Not met	See below	High risk**	FDA002145-002147	
(see above), Aureo S 700, Aureomycin	Vol. II	035-688, 035-805, 048-761	Not met	FDA002333	High risk**	FDA002325-002333	
Aureomix S 700 G	Vol. II	041-649	Not met	FDA003898	High risk	FDA003898	
Aureomix S 700 B	Vol. II	041-653	Not met	FDA003908-003910	Not enough information	FDA003910	
Penicillin 100/Penicillin G Procaine 50	Vol. II	046-666	Not met	FDA004026/FDA004029	High risk**	FDA004024-004027	
Pencillin G Procaine 50%	Vol. II	046-668	Not met	FDA004320-004322, FDA004324	High risk**	FDA004326-004330	
Chlormax products, Micro CTC 100	Vol. II	046-699	Not met	FDA004453-004454	High risk**	FDA004459	
Chlorachel 50, Pfichlor products	Vol. II	049-287	Not met	FDA0044486	High risk**	FDA004469-004476	
Rainbrook Broiler Premix No. 1	Vol. II	049-462	Not met	FDA004494	High risk**	FDA004491-004493	Withdrawn, Green book/Animal Drugs@ FDA

Name of product	Volume of FDA Review	NADA Number	Met 1973 Safety Criteria	1973 Safety Criteria Citation	Risk Estimation (Guidance 152)	Risk Citation	Additional Information
Aureomycin Soluble Powder	Vol. II	055-020#	Not met	FDA004521	Not enough information	FDA004522	May not be applicable to 1973 criteria, Animal Drugs @FDA
Penicillin G Potassium	Vol. II	055-060*	N/A	FDA004532	High risk	FDA004533-004536	1973 criteria not applicable FDA004533
Tetracycline Soluble Powder	Vol. III	065-496#	Not met	FDA007239	High risk**	FDA004619-004623	May not be applicable to 1973 criteria, Animal Drugs @FDA
ChlorMax SP products, Chlorachel 250	Vol. III	091-668	Not met	FDA004730	High risk**	FDA004724-04730	
CLTC 100 MR, CLTC 70	Vol. III	092-287	Not met	FDA004766	Not enough information	FDA004774	
OXTC products, Terramycin products	Vol. III	095-143	Not met	FDA004811	Not enough information	FDA004811-FDA004812	
Pfichlor 100S Milk Replacer	Vol. III	100-901	Not met	FDA004818	High risk	FDA004819	
Terramycin Premix	Vol. III	103-758	Not met	FDA004838	Not enough information	FDA004839	Withdrawn,[3] Animal Drugs@FDA
Pennchlor SP 250/ Pennchlor SP 500	Vol. III	138-934	Not met	FDA004849-004850, FDA004872	High risk**	FDA004872-004876	
Oxytetracycline products, Pennox products	Vol. III	138-938	Not met	FDA004898	Not enough information	FD004899-4902	
CSP 250/CSP 500	Vol. III	039-077	Not met	FDA006977	High risk**	FDA006973-006977	

Name of product	Volume of FDA Review	NADA Number	Met 1973 Safety Criteria	1973 Safety Criteria Citation	Risk Estimation (Guidance 152)	Risk Citation	Additional Information
Chloratet 100, Chloratet 90	Vol. III	048-480	Not met	FDA007160	High risk	FDA007160	
CLTC products	Vol. III	092-286	Not met	FDA007259	Not enough information	FDA007259	
Aureomix S 700-A, Aureomix S 700-D, Aureomix S 700-E, , Aureomix S 700-F, Aureomix S 700-H	Vol. III	041-647 041-648 041-650 041-651 041-654	Not met	FDA007294	Not enough information	FDA007294	
Quratermaster Dry Cow Treatment	Vol. III	055-028*	N/A	FDA007729	High risk**	FDA007729-007738	1973 criteria not applicable (Vol. III FDA007723)
Aureomix S 700-C 2	Vol. IV	041-652	Not met	FDA009391	High Risk	FDA009391	

APPENDIX II

EVIDENCE OF MARKETING

1. Pennchlor SP 250 (NADA 138-934) – evidence of marketing through a feed company

"Pennchlor SP 250 – Product Description," Feed Products and Company South, http://www.feedproducts.net/products/pennchlor-SP-250.htm, accessed November 25, 2013.

"Pennchlor SP-250- Specifications," Feed Products and Company South, http://www.feedproducts.net/documents/PennchlorSP250.pdf, accessed November 24, 2013.

2. Aureomix 500 (NADA 035-688) – evidence of marketing through an animal pharmaceutical company

"Product inserts – Aureomix 500," Zoetis, https://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 25, 2013.

"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/MSDS_PI/PI/Aureomix_500.pdf, accessed November 25, 2013.

3. Penicillin 100 (NADA 046-666) – evidence of marketing through an animal pharmaceutical company

"Product inserts – Penicillin 100," Zoetis, https://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 26, 2013.

"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/MSDS_PI/PI/Penicillin_100.pdf, accessed November 25, 2013.

4. Chloratet (NADA 048-480) – evidence of marketing through a supplier company

"PALS feed additives and medication products catalog" PALS USA, http://palsusa.com/files/PALSMedCatalog.pdf, last accessed November 21, 2013.

5. Terramycin (NADA 008-622) – evidence of marketing of the generic (ANADA 200-026) based on this NADA by a supplier company

"Supplemental Abbreviated New Animal Drug Application" Food and Drug Administration, http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm061570.pdf, last accessed on November 24, 2013.

"Terramycin 343-soluble powder" Revival Animal Health, http://www.revivalanimal.com/Terramycin-343-Soluble-Powder-Generic.html, last accessed on November 25, 2013.

6. Aureomycin NADA (48-761) – evidence of marketing by an animal pharmaceutical company

"Product insert - Aureomycin 50, 90, 100 Granular," Zoetis, https://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 25, 2013.

"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/MSDS_PI/PI/Aureomycin_50_90_100_Granular-swine.pdf, accessed November 25, 2013.

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"Pennox 100MR – Product Description," Feed Products and Company South, http://www.feedproducts.net/products/pennox-100-MR.htm, accessed November 25, 2013.

"Pennox 100MR- Specifications," Feed Products and Company South, last modified October 2010, http://www.feedproducts.net/documents/Pennox100MR.pdf, accessed November 24, 2013.

8. CLTC (NADA 92-287) – Evidence of marketing by a supplier and by inclusion in a USDA risk management program

"CLTC-100 MR" Animart Dairy and Livestock solutions, http://www.animart.com/store/cltc-100-mr-50lb-drum/, accessed November 24, 2013.

"CLTC 100MR" Food Animal Residue Avoidance Databank, http://www.farad.org/vetgram/ProductInfo.asp?byNada=092-287, accessed November 24, 2013.

9. Chlormax (NADA 46-669) – Evidence of marketing by an animal pharmaceutical company

"Product inserts – Chlormax," Zoetishttps://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 25, 2013.

"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/PublishingImages/Poultry%20Literature%20Library/US-EN/ChlorMax_Product_Profile_ZP130030_EN_Zoetis.pdf, accessed November 25, 2013.

Note: All products above are also listed by brand name in Feed Additive Compendium.

APPENDIX III

Selection of correspondence between Center for Veterinary Medicine and sponsors on FDA review conclusions.

NADA 046-666

Excerpt from letter sent to sponsor: "The administrative record does not contain sufficient information to alleviate the Center [for Veterinary Medicine]'s concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance."
Food and Drug Administration, Letter from FDA to Sponsor of NADA 046-666, May 26, 2004, Vol. III: FDA007516.

Excerpt from sponsor response: "[W]e wish to advise CVM of our strongly held view that these products, with the current claims, remain safe and effective…. The amendment to the FY 2001 appropriation directed a review of previous approvals. It did not alter the standards applicable to withdrawing approval to allow withdrawal based on nonscientifically based precautionary grounds. We believe the agency should be able to separate the justifiable concerns related to the development of antibiotic resistant human pathogens and discern that [the sponsor's] subtherapeutic penicillins are not the source of, or even a measurable contributor to, this public health issue."
Food and Drug Administration, Letter from Sponsor (of NADA 046-666, 035-688 039-077, and 091-668) to FDA, October 22, 2004, Vol. III: FDA008180-2.[iv] *Note: The sponsoring company sent the same letter as a response to FDA's letters regarding four separate NADAs.*

NADA 046-668

Excerpt from letter sent to sponsor: "The administrative record does not contain sufficient information to alleviate the Center [for Veterinary Medicine]'s concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance."
Food and Drug Administration, Letter from FDA to Sponsor of NADA 046-668, received May 26, 2004, Vol. III: FDA007518.

Excerpt from the sponsor response: "[The sponsor] has been unable to make a decision on how to proceed on this issue. Although [Center for Veterinary Medicine] did supply us with a copy of the presentation given at the meeting, very little information was presented on the hazard characterization. In addition, it would be helpful for us to see a more complete description of the risk assessment so that we can determine what additional data may be collected/supplied to help support a more thorough evaluation."
Food and Drug Administration, Letter from Sponsor (of NADA 046-668) to FDA, November 15, 2004, Vol. III: FDA008950.

NADAs 035-688, 039-077, 091-668

Excerpt from letter sent to sponsor: "The administrative record does not contain sufficient information to alleviate the Center [for Veterinary Medicine]'s concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance."
Food and Drug Administration, Letter from FDA to Sponsor of NADA 035-688, 039-077, and 091-668, May 26, 2004, Vol. III: FDA007522.

Excerpt from sponsor response: … We wish to advise CVM of our strongly held view that these products, with the current claims, remain safe and effective… The amendment to the FY 2001 appropriation directed a review of previous approvals. It did not alter the standards applicable to withdrawing approval to allow withdrawal based on nonscientifically based precautionary grounds. We believe the agency should be able to separate the justifiable concerns related to the development of antibiotic resistant human pathogens and discern that [the sponsor's] subtherapeutic penicillins are not the source of, or even a measurable contributor to, this public health issue."
Food and Drug Administration, Letter from Sponsor (of NADA 046-666, 035-688 039-077, and 091-668) to FDA, October 22, 2004, Vol. III: FDA008180-2.[iv]

NADA 138-934

Excerpt from letter sent to sponsor: "The administrative record does not contain sufficient information to alleviate the Center [for Veterinary Medicine]'s concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance."
Food and Drug Administration, Letter from FDA to Sponsor of NADA 138-934, May 26, 2004, Vol. III: FDA007526.

Excerpt of FDA's summary of the sponsor's response: "The firm submitted a letter dated July 31, 2006 stating that they would remove the 'growth promotion and increased feed efficiency' indication from their label, as long as the other firms with the same product and indication did so as well…The firms also submitted (January 4, 2005) the results of a literature search… Specific information to address the data gaps in the microbial food safety assessment was not retrieved by the search terms used by the firm."
Food and Drug Administration, Microbial Food Safety Team (HFV-157), Brown Amendment Review of NADA 138-934, Vol. III: FDA004849-50

Endnotes

1 As noted, we use the term "nontherapeutic use" to refer to the use of antibiotics to speed up animal growth and prevent diseases. Antibiotics are typically administered for these purposes to large groups of animals for extended periods of time. We use "therapeutic" use to mean the use of antibiotics to treat sick animals or to control disease outbreaks in rare circumstances. FDA regulations refer to growth promotion and disease prevention uses as "subtherapeutic." 21 C.F.R. § 558.15.

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43 FDA did not respond to the FOIA request until NRDC filed a lawsuit; subsequently a settlement was reached and documents were made available.

44 *Natural Resources Defense Council v. United States Food and Drug Administration*, 884 F.Supp.2d 127, 131-32 (S.D.N.Y. 2012) (hereinafter "*NRDC v. FDA*").

45 FDA also reviewed two antibiotics products that were not approved for use *in animal feed or water*, and determined that they are "high risk" under the 2003 guidelines discussed further below. The antibiotic products are approved for intramammary application to dairy cows (NADA 055-028), and for treatment use (NADA 055-060). They were not required to meet the 1973 safety requirements, which focused on the safety of antibiotic feed additives. FDA examined the topical antibiotic because it was approved for preventive use, but it is not clear why FDA reviewed the antibiotic product approved for treatment. It remains unclear if and how safety for human health was established for these two antibiotic products; Food and Drug Administration, Microbiologist's Review of NADA 055-028, Vol. III, FDA007723-7739; Food and Drug Administration, Microbiologist's Review of NADA 055-060, Vol. II, FDA004531-4537.

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48 Food and Drug Administration, Microbiologist's Review of NADA 065-123, Tetracycline Soluble Powder, Vol. III, FDA004566-67.

49 Appendix I, Column 4, shows which antibiotics failed to meet the 1973 criteria.

50 *NRDC v. FDA*, 884 F.Supp.2d at 133.

51 Three antibiotic products (NADA 065-496, 055-020, and 008-622) are additives approved for administration to animals for fewer than 14 days and the 1973 criteria may not apply. "In the past, FDA has referred to ''subtherapeutic'' uses at various times to include: (1) 'Increased rate of gain, disease prevention, etc.' (Ref. 7); (2) 'any use of an antibacterial drug continuously in feed for longer than 14 days' (Ref. 23); and (3) 'lower levels than therapeutic levels needed to cure disease.' (Refs. 1 and 2)." Withdrawal of NOOH; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79697, 79700 (Dec. 22, 2011). See Appendix I, Column 4 and 8, show which antibiotics failed to meet the 1973 criteria and if the 1973 criteria were applicable.

52 *See* Food and Drug Administration, Microbiologist's Review of NADA 008-804, Vol. I, FDA002097, FDA002114. The approved NADA covers several versions of the same feed additive, a Terramycin Animal Mix.

53 See Appendix I, column 5.

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58 *See* Food and Drug Administration, Approved Animal Drug Products Online (Green Book), http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm) (last accessed January 15, 2014). The two drugs that were voluntarily discontinued or withdrawn are Rainbrook Broiler Premix No. 1 (NADA No. 49-462) and Terramycin Premix (NADA No. 103-758). Food and Drug Administration, Microbiology Food Safety Review of NADA 49-462, at 6-7, Vol. II, FDA004486-87; Food and Drug Administration, Microbial Food Safety Review of NADA 103-758, at 1-2, Vol. III, FDA004838-39. Please note that the FDA database at AnimalDrugs@FDA (http://www.accessdata.fda.gov/scripts/animaldrugsatfda/) lists NADA 103-758 as voluntarily withdrawn; however, the official "Green Book" does not.

59 *NRDC v. FDA*, 884 F.Supp.2d at 133 (citing 42 Fed.Reg. 43,772, 43,774 (Aug. 30, 1977)).

60 Food and Drug Administration, Guidance for Industry No. 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern,* 2003, www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf (accessed October 10, 2013) (hereinafter, "Guidance #152").

61 Food and Drug Administration, Microbiologist's Review of NADA 134-938 "Part I: Summary of Findings," Vol. III, FDA004872. ii. *Id.*

62 *Id.*

63 *See* Appendix III, NADA 138-934, Excerpt from FDA letter sent to sponsor.

64 *See* Approved usages for NADA 134-938, Vol. III, FDA004847-48; 21 C.F.R. § 558.145.

65 *See* Food and Drug Administration, Microbiologist's Review of NADA 134-938, at 24-25, Vol. III, FDA004876-77.

66 FDA's current statements on the issue of preventive claims, in non-binding policy documents such as Guidance #213, explain that FDA does not consider prevention uses to be subtherapeutic anymore, contradicting its own binding regulations, 21 C.F.R. § 558.15, despite the fact that the claims may overlap in the use allowed.

67 *See* Approved usages for NADA 134-938, Vol. III, FDA004847-48; 21 C.F.R. § 558.145.

68 *See* Appendix III, NADA 138-934, Excerpt from FDA's summary of the sponsor's response; *see also* Food and Drug Administration documents concerning NADA 134-938, Vol. III, FDA004846-4885.

69 *See* Food and Drug Administration documents concerning NADA 134-938, Vol. III, FDA004846-4885

70 *See* Appendix II.

71 "From CVM to the sponsor… The letter indicates that considerable concern is being expressed by public health officials and representatives of the human health care community regarding the emergence of antimicrobial resistance. Attention is being drawn to the use of antimicrobials in animals as a source of the increasing resistance… The sponsor is asked to voluntarily withdraw their product." Food and Drug Administration, Microbiologist's Review of NADA 046-666, Part I: Review of Administrative Record, Vol. II, FDA003974.

72 "From CVM to the sponsor… The letter also states that the products subject to this NADA were determined to be effective for increasing rate of growth and improving feed efficiency under the DESI review, the products failed to meet antimicrobial resistance criteria established under 21 CFR 558.15 and as a result…were proposed for withdrawal via an NOOH published in 1977." Food and Drug Administration, Microbiologist's Review of NADA 046-666, Part I: Review of Administrative Record, Vol. II, FDA003974.

73 "It is interesting to note that although the sponsor makes the following statement in the body of their report, 'Among the non-infected groups, there were significantly more ampicillin, chloramphenicol, nitrofurantoin and kanamycin resistant *E. coli* in the treated group than in the control group,' this does not appear in the conclusions section of their report." Food and Drug Administration, Microbiologist's Review of NADA 046-666, Review of Data Pertaining to 558.15, Vol. II, FDA004019; *see* Letter from FDA to Sponsor of NADA 046-666, May 26, 2004, Vol. III, FDA007515 (noting that CVM concluded that "there were still questions about the observed increases in resistant *Salmonella* and *E. coli")*.

74 "From sponsor: 'We are of course, aware of the renewed controversy over the use of certain antibacterials in animals; however, we continue to believe that when their safety is called into question, new animal drug approvals should only be withdrawn when there is sound scientific evidence for so doing. Mere speculation and theory should not be a basis for withdrawal of approval.'" Food and Drug Administration, Microbiologist's Review of NADA 046-666, Part I: Review of Administrative Record, Vol. II, FDA003974.

75 *See* Food and Drug Administration documents concerning NADA 046-666, Vol. II, FDA003946-4075.

76 *See* Appendix III, NADA 046-666, Excerpt from FDA letter sent to sponsor.

77 *Id.*

78 "Product inserts – Penicillin 100," Zoetis, last modified 2013, https://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 26, 2013;"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/MSDS_PI/PI/Penicillin_100.pdf, accessed November 25, 2013;"PALS feed additives and medication products catalog" PALS USA, http://palsusa.com/files/PALSMedCatalog.pdf, last accessed November 21, 2013.

79 *NRDC v. FDA*, 884 F.Supp.2d at 132-33.

80 Carol Cogliani, Herman Goossens, and Christina Greko, *Restricting Antimicrobial Use in Food Animals: Lessons from Europe*, Microbe Magazine (June 2011), www.microbemagazine.org/index.php?option=com_content&view=article&id=3458:restricting-antimicrobial-use-in-food-animals-lessons-from-europe&catid=752&Itemid=995.

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82 *NRDC v. FDA*, 884 F.Supp.2d at 133.

83 *Id.* at 133-34.

84 *Id. generally*; *Natural Resources Defense Council v. U.S. Food and Drug Administration*, 872 F.Supp.2d 318 (S.D.N.Y. 2012).

85 Guidance #152.

86 Government Accountability Office, Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals 24 (September 2011), http://www.gao.gov/assets/330/323090.pdf; Food and Drug Administration, Guidance for Industry No. 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern* (October 23, 2003), www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf .

87 Food and Drug Administration, Guidance for Industry No. 213 , *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209 (December 2013),* http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm299624.pdf (hereinafter, "Guidance #213").

88 Food and Drug Administration, Guidance for Industry No. 209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* 21 n.5 (*April 13* 2012), http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf.

89 Government Accountability Office, Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals 28 (September 2011), http://www.gao.gov/assets/330/323090.pdf.

90 21 C.F.R. § 558.15.

Method and Appendices endnotes

i For all of the antibiotic feed additives listed in this appendix, FDA did not have sufficient data to conduct a thorough risk assessment. However, for 18 antibiotic feed additives, it had sufficient information to carry out an abbreviated risk assessment. Even for these 18 additives, the assessment was more thorough for some additives than for others. "High risk" indicates that FDA scientists conducted a basic risk assessment. "High risk**" indicates that FDA conducted a more detailed assessment considering release, exposure, and consequence. See the following for example: Food and Drug Administration, Assessment of the Administrative Record using Guidance for Industry #152 – NADA 091-668, Vol. III, FDA004724-4730. For the other 12 additives, FDA concluded that it simply did not have sufficient information to be able to make any determination about risk. These additives are thus not shown to be safe.

ii *Two antibiotic products (NADA 055-060 and NADA 055-028) are not included in the 30 antibiotic feed additives discussed in the main text. #Three antibiotic products (NADA 065-496, 055-020, and 008-622) are additives approved for administration to animals for fewer than 14 days as indicated in Animal Drugs @ FDA database and the 1973 criteria may not be applicable.. (See main text for further information). Animal Drugs @ FDA database, http://www.accessdata.fda.gov/scripts/animaldrugsatfda/

iii Please note that the FDA database at AnimalDrugs@FDA (http://www.accessdata.fda.gov/scripts/animaldrugsatfda/) lists NADA 103-758 as voluntarily withdrawn; however, the official "Green Book" does not.

iv Note that the same sponsor is associated with NADAs 046-666, 035-688, 039-077, and 091-668. The sponsor sent only one letter in response to FDA's concerns and comments on all four NADAs.

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Drug critic slams FDA over antibiotic oversight in meat production

Mon, Jan 27 2014

By P.J. Huffstutter and Brian Grow

(Reuters) - The United States Food and Drug Administration allowed 18 animal drugs to stay on the market even after an agency review found the drugs posed a "high risk" of exposing humans to antibiotic-resistant bacteria through food supply, according to a study released Monday by the Natural Resources Defense Council.

The study by the NRDC, a non-governmental group that criticizes the widespread use of drugs in the meat industry, is the latest salvo in the national debate over the long-standing practice of antibiotic use in meat production. Agribusinesses say animal drugs help increase production and keep prices low for U.S. consumers, while consumer advocates and some scientists raise concerns over antibiotic-resistant bacteria.

The FDA stirred the debate late last year when it unveiled guidelines for drug makers and agricultural companies to voluntarily phase out antibiotic use as a growth enhancer in livestock. The agency said those guidelines were an effort to stem the surge in human resistance to certain antibiotics.

But the NRDC's study found the FDA took no action to remove 30 antibiotic-based livestock feed products from the market even after federal investigators determined many of those antibiotics fell short of current regulatory standards for protecting human health.

NRDC studied a review conducted by the FDA from 2001 to 2010 that focused on 30 penicillin and tetracycline-based antibiotic feed additives. The drugs had been approved by regulators to be used specifically for growth promotion of livestock and poultry - essentially to produce more meat to sell.

The FDA, in a statement, said it began a review of older, approved penicillin and tetracycline products in 2001, and issued letters to companies who made the products asking for additional safety data.

"Based on its review of this and other information, the Agency chose to employ a strategy that would more broadly address the concerns about the production use of medically important antimicrobials in food-producing animals," the FDA said.

Some academics specializing in antibiotic resistance criticized the NRDC's study, saying that the findings do not reflect current regulatory standards because some of the drugs have been withdrawn from the market.

They also say that the study assessed FDA safety guidelines that have been replaced with more stringent standards.

Dr. Randall Singer, associate professor of epidemiology at the University of Minnesota, told Reuters that drug makers and the U.S. livestock industry are phasing out antibiotics used principally for growth promotion.

"We have been telling (both of) them for years to be prepared for the elimination of growth promotion and feed efficiency labeling because you cannot make that change overnight," said Singer, who reviewed the NRDC report for Reuters.

The NRDC, which reviewed more than 3,000 pages of documents through a federal Freedom of Information Act request, said it found evidence to suggest nine of the drugs are still on the market and used by livestock producers. Reuters was not able to independently verify that detail immediately.

One of the drugs still on the market is animal health company Zoetis Inc's Penicillin G Procaine 50/100, which is fed to poultry in part to aid in weight gain.

The NRDC says the FDA twice laid out its concerns to that drug maker that the product failed to meet safety regulations. The unnamed original sponsor of the drug apparently disputed the regulators' findings, according to excerpts from a 1997 letter sent to the FDA and included in documents obtained by the NRDC.

A spokeswoman for Zoetis, a unit of Pfizer Inc that owns the drug today, said the company already is working to phase out use of the drug for growth promotion as part of the new FDA guidelines and is planning to relabel the drug for more limited purposes.

Once companies remove farm-production uses of their antibiotics from drug labels, it would become illegal for those drugs to be used for those purposes, Deputy FDA Commissioner Michael Taylor told reporters recently. Although the program is meant to be voluntary, Taylor said the FDA would be able to take regulatory action against companies that fail to comply.

In its statement on Monday, the FDA said it is "confident that its current strategy to protect the effectiveness of medically important antimicrobials, including penicillins and tetracyclines, is the most efficient and effective way to change the use of these products in animal agriculture."

NRDC attorney Avinash Kar, one of the study's authors, said the group's findings raise questions about whether regulators will be effective in enforcing the new guidelines.

"The FDA's failure to act on its own findings about the 30 reviewed antibiotic feed additives is part of a larger pattern of delay and inaction in tackling livestock drug use that goes back four decades," Kar told Reuters.

(Reporting By P.J. Huffstutter in Chicago and Brian Grow in Atlanta; Editing by David Greising, Amanda Kwan and Kenneth Maxwell)

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ATTACHMENT 20

NRDC REPORT

APRIL 2014
R:14-03-A

Generally Recognized as Secret:
Chemicals Added to Food in the United States

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EXECUTIVE SUMMARY

When President Eisenhower signed the Food Additives Amendment of 1958, he established a regulatory program intended to restore public confidence that chemicals[a] added to foods are safe. In the intervening 56 years, the basic structure of the law has changed little. However, the regulatory programs the U.S. Food and Drug Administration (FDA) established to implement the law have fallen behind over time as the agency strived to keep up with the explosion in the number and variety of chemicals in food, and to manage its huge workload with limited resources.

The 1958 law exempted from the formal, extended FDA approval process common food ingredients like vinegar and vegetable oil that are "generally recognized as safe" (GRAS). It may have appeared reasonable at the time, but that exemption has been stretched into a loophole that has swallowed the law. The exemption allows manufacturers to make safety determinations that the uses of their newest chemicals in food are safe without notifying the FDA. The agency's attempts to limit these undisclosed GRAS determinations by asking industry to voluntarily inform the FDA about their chemicals are insufficient to ensure the safety of our food in today's global marketplace with a complex food supply. Furthermore, no other developed country in the world has a system like GRAS to provide oversight of food ingredients.

Because of the apparent frequency with which companies make GRAS safety determinations without telling the FDA, NRDC undertook a study to better understand companies' rationale for not participating in the agency's volutnary notification program. First, we built a list of companies and the chemicals they market. Then we reviewed public records, company websites, and trade journals to identify additives that appear to be marketed in the U.S. pursuant to an undisclosed GRAS determination, i.e. without notification to the FDA.

All told, we were able to identify 275 chemicals[a] from 56 companies that appear to be marketed for use in food based on undisclosed GRAS safety determinations. This is likely the tip of the iceberg—we previously published in an industry journal an estimate that there have been 1,000 such secret GRAS determinations.[1] For each chemical we identified in this study, we did not find evidence that FDA had cleared them.

In addition, using the Freedom of Information Act (FOIA), we obtained from the FDA copies of communications between the agency and companies who voluntarily sought agency review of their GRAS determinations. We found this glimpse into the review process shows that often the agency has had serious concerns about the safety of certain chemicals, and that companies sometimes make safety decisions with little understanding of the law or the science. As discussed later, companies found their chemicals safe for use in food despite potentially serious allergic reactions, interactions with common drugs, or proposed uses much greater than company-established safe doses.

On those occasions when the FDA is asked to review a GRAS determination, the agency rejects or triggers withdrawal of about one in five notices. Moreover, the public has even less information about the many substances with GRAS determinations that are never submitted to the agency in the first place—and which may pose a much greater danger. It is often virtually impossible for the public to find out about the safety—or in many cases even the existence—of these chemicals in our food.

"Generally Recognized as SECRET" rather than "Generally Recognized as SAFE" is a better name for the GRAS loophole that has allowed manufacturers to sanction the use of hundreds of chemicals in food that Americans eat every day.

a We use the term "chemicals" to apply to the products sold by additive manufacturers. They may be individual substances or mixtures of substances. They are sometimes referred to as substances, additives, or ingredients, which, in reality, are all chemicals or mixtures of them. They may be extracted from natural products or synthesized from other chemicals.

"We cannot require anything, as this is a voluntary program and we don't want to frighten anyone away. Having said that, we would typical [sic] tell any notifier that their submission would have to address the total dietary exposure from new and current uses, [h]ow else could you conclude that the uses were safe, without a notion of what total exposure is[?]"[2]

FDA reviewer of GRAS determination submitted by manufacturer

NRDC believes that "Generally Recognized as SECRET" rather than "Generally Recognized as SAFE" is a better name for the GRAS loophole. A chemical additive cannot be "generally recognized as safe" if its identity, chemical composition, and safety determination are not publicly disclosed. If the FDA does not know the identity of these chemicals and does not have documentation showing that they are safe to use in food, it cannot do its job.

In an increasingly global marketplace where many additives and foods are imported into the United States, this loophole presents an unsettling situation that undermines public confidence in the safety of food and calls into question whether the FDA is performing its duty to protect public health.

The problem is rooted in a law adopted in 1958 when Dwight Eisenhower was president and Elvis was drafted. It is time for the FDA and Congress to fix the problems. In the meantime, consumers need to demand that their grocery stores and their favorite brands sell only those food products with ingredients that the FDA has found to be safe.

GRAS: HOW THE LOOPHOLE SWALLOWED THE LAW

Over the last five years, there have been many news stories about unsafe foods that have sickened people. There have been a few reports of acute health problems related to chemicals added to foods, such as energy drinks containing a mixture of caffeine and alcohol, or rice with excessive amounts of the vitamin niacin. But chemicals added to food are more likely to be associated with health problems that may appear after years of frequent food and beverage consumption. These problems are often chronic in nature. The FDA is unlikely to detect an adverse health effect (short of immediate serious injury) unless companies notify it about the chemical and its use in food.

That is why Congress required that a chemical's intentional use in food be determined to be safe prior to its entering the marketplace.[3] In 1958 President Eisenhower signed the Food Additives Amendment to the Federal Food Drug and Cosmetic Act to address these concerns.[4] The law presumed that a chemical intentionally added to food was potentially unsafe and required that no chemical be used without a "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[5] Congress required food companies to file a "food additive petition" as the primary means by which to get an FDA approval of a chemical's use in food. If the agency did propose to approve the chemical, it would inform the public and request comments before adopting a regulation allowing the use.[6] The system was designed at a time when an estimated 800 chemical additives were in use, far fewer than the more than 10,000 allowed today.[7,8]

"The next day, [notifier] called and asked whether [notifier] would have an option to withdraw the notice rather than receive a letter that the notice did not provide a basis for a GRAS determination. I replied that this was an option. On September 4, [notifier] asked whether [notifier] could still sell its [name] product if it withdrew its GRAS notice. Consistent with my response to her earlier question about marketing [name], I said yes."[9]

FDA officer summarizing telephone conversations with manufacturer regarding its GRAS notice review

Determining that a chemical's use in food is and remains safe typically involves significant professional judgment. Rarely are these decisions clear cut; there is no bright line. So who decides is critical. Congress concluded that the FDA would make all safety decisions, except in the most obvious situations in which a chemical's use in food was "generally recognized as safe." This is known as the GRAS exemption. Examples include such common food ingredients as oil and vinegar. When a chemical's use was determined to be GRAS, the FDA did not need to adopt a regulation specifically allowing its use, and the formal public notice and comment rulemaking process was not required.[10] In other words, the

chemical didn't need premarket approval by the agency, and manufacturers could use it without delay. To qualify as GRAS, a chemical's safety had to be generally recognized by knowledgeable scientists, as borne out by published safety studies unless commonly and safely used before 1958.[11]

However, the FDA and the food industry interpreted the law as allowing manufacturers to determine that a chemical's use in food was safe without notifying the agency.[12] As a result, the identity of the chemical and the foods in which it was being used could be unknown to the public and the agency. Since 1958, an estimated 1,000 chemicals have been determined as GRAS by manufacturers and have been used in food without any approval or review by the FDA.[13] The exemption has become a loophole that has swallowed the law.

THE FDA'S ATTEMPTS TO LIMIT UNDISCLOSED INDUSTRY SAFETY DECISIONS

Recognizing the problem of undisclosed safety decisions, the FDA adopted regulations in 1972 inviting manufacturers to voluntarily submit "GRAS affirmation petitions" in a rulemaking process that was similar to the one for food additive petitions, but without statutory deadlines for action.[14] Companies sought FDA's approval, it appears, because their product would be more widely accepted by food manufacturers.

By the early 1990s, confronted with limited resources and an increasingly complicated and time-consuming formal rulemaking process, the FDA faced an overwhelming backlog of unresolved reviews.[15] In response, the agency proposed a rule in 1997 to replace the 1972 GRAS petition process with a less formal review process that did not involve adopting regulations for specific chemicals.[16] The next year, the FDA began accepting voluntary notifications from the companies that summarized the safety evidence and issuing decision letters.[17] In some cases, these decision letters are often cited by the companies as evidence of FDA clearance, although the agency maintains that the letters are informal and do not constitute approval. This process, however, largely cuts the public and outside experts out of meaningful participation in decision making. The proposed rule has never been finalized despite its wide use by industry and the FDA.[18] Since 2000, almost all new chemicals have passed through the loophole rather than being subjected to the food additive petition process established by Congress in 1958.

In 2010, the Government Accountability Office (GAO), the nonpartisan investigative arm of Congress, scrutinized the agency's GRAS program and found serious shortcomings. It concluded that "FDA's oversight process does not help ensure the safety of all new GRAS determinations" and that "FDA is not systematically ensuring the continued safety of current GRAS substances."[19]

Given these concerns, NRDC sought to identify examples of chemicals marketed pursuant to undisclosed GRAS safety determinations, procure such safety determinations from companies, and examine why companies choose to forgo even the voluntary FDA notification process.

CLAIMING GENERAL RECOGNITION WHILE AVOIDING DISCLOSURE

As mentioned above, some 1,000 chemicals have been determined by manufacturers to be safe for use in food without FDA review or approval. Some of them, like artificial *trans* fat, were self-certified by industry as safe ingredients decades ago and are well known.

NRDC's investigation focused on newer, less known chemicals marketed as GRAS for use in food in the United States since 1997. We looked at situations in which:

- the manufacturer opted to rely on an undisclosed GRAS determination, without using the FDA's voluntary notification process;
- the manufacturer notified the FDA, and the agency subsequently rejected the company's GRAS notice;
- the manufacturer notified the FDA but subsequently withdrew its notice from FDA review. (We will discuss the problems with withdrawal of notices later.)

Our investigation began with a list of companies and chemicals from three sources:

- the little-known (outside of the food additives industry) web-based "GRAS Self-Determination Inventory Database," compiled by a consulting firm that makes GRAS safety determinations for industry;[20]
- consultants who provided company names based on their experience at food industry trade shows;
- withdrawn or rejected notices in FDA's GRAS Notice Inventory.[21]

Overall, we identified 398 chemicals marketed by 163 companies that appear to be marketed in the U.S. based on GRAS determinations not reviewed by FDA.[b]

For each chemical, we sought a copy of the written documentation of the GRAS safety determination required by FDA's regulations (21 CFR §170.30), which companies must have completed before marketing a product as GRAS. This documentation must provide the chemical composition of the substance, describe how it is made, estimate how much people are likely to consume (exposure), and describe what is known about the chemical's potential hazards. Unless a chemical was commonly and safely used before 1958, the key studies evaluating the hazards ordinarily must be published, preferably in a peer review journal but the FDA does not exclude publication on a company's website. While identifying a key study is helpful, it is not a substitute for providing the full safety determination.

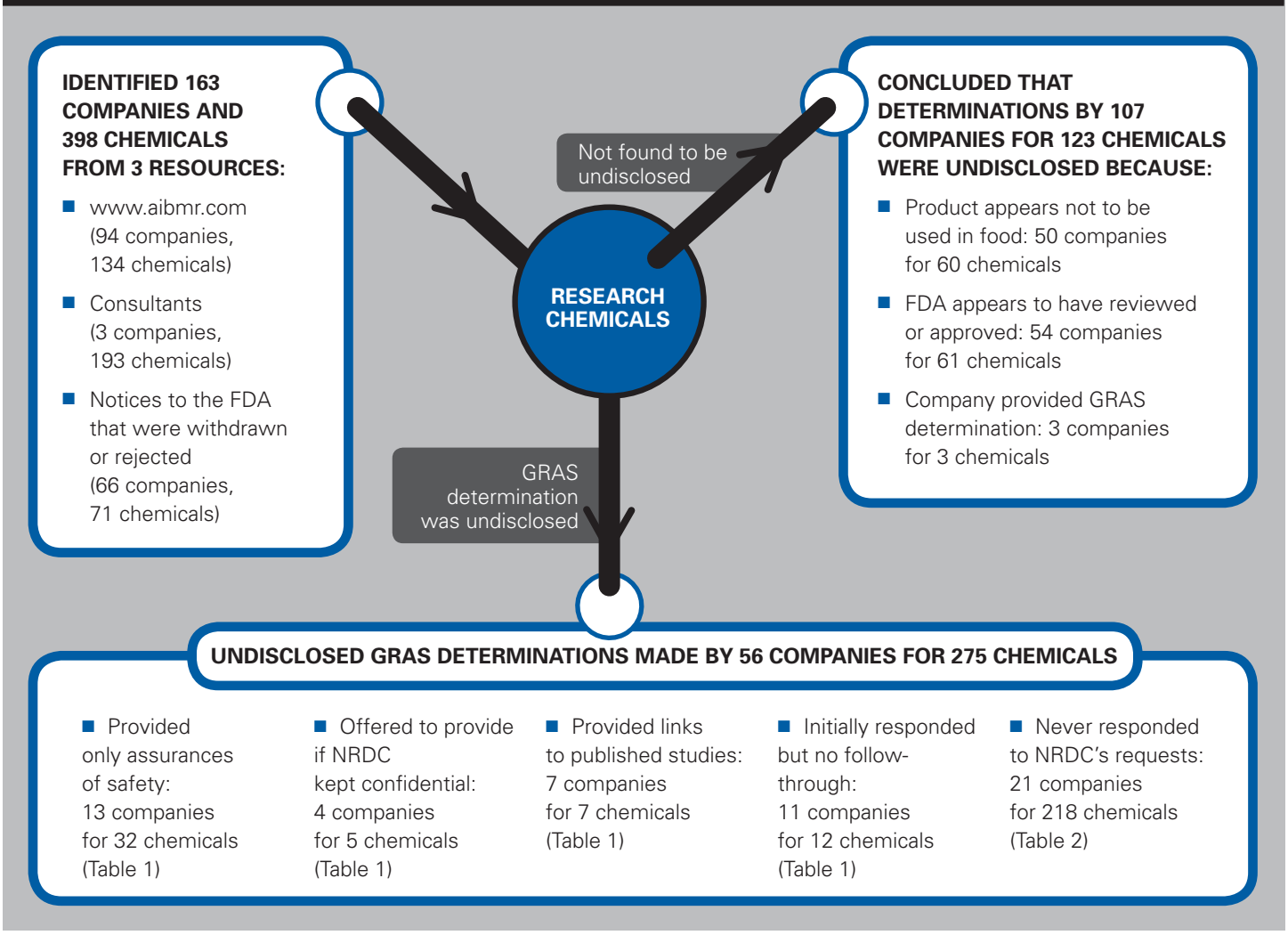
Where a company appeared to be marketing a chemical for use in the United States as GRAS without final FDA review, NRDC contacted the company to request a copy of the undisclosed safety determination. If the company declined or did not respond to our request, we classified the GRAS determination as "undisclosed". Also, if the company did not provide us with a revised GRAS determination that addressed the FDA's concerns after the agency rejected the company's notice, or if the company withdrew its notice before the agency made a final decision, we considered the GRAS determination to be undisclosed.

"GENERALLY RECOGNIZED AS SECRET"

All told, 56 companies appear to rely on undisclosed GRAS safety determinations for 275 chemicals (Figure 1):

- 35 companies selling 57 chemicals responded to our inquiries, but did not provide their GRAS safety determination (Table 1).
- 21 companies selling 218 chemicals did not respond to our repeated inquiries (Table 2).

Figure 1: Process to Identify and Evaluate Companies and Chemicals



b Where chemicals had similar names but different manufacturers, we treated them as separate chemicals.

Table 1: Companies with undisclosed GRAS determinations that responded to NRDC						
Company	**Country**	**No. of Chemicals**	**Declined Requests**	**Only if Confidential**	**Only Gave Studies**	**No Follow-up**
Albion	USA	2	Yes	Yes		
Aloecorp	Korea	1				Yes
BASF	Germany	2				Yes
BioCell Technology	USA	1	Yes			
Bioriginal	Canada	1	Yes	Yes	Yes	
ChromaDex	USA	1				Yes
Cyvex Nutrition	USA	3	Yes			
DSM	Netherlands	8	Yes			
Embria Health Sciences	USA	1	Yes			
ESM Technologies	USA	1	Yes		Yes	
Frutarom Health	Israel	1				Yes
Genosa	Spain	1	Yes			
GTC Nutrition	USA	1				Yes
HG&H Pharmaceuticals (Pty) Ltd.	South Africa	1	Yes			
House Wellness Foods	Japan	1	Yes			
InterHealth Nutraceuticals	USA	4	Yes			
Ixoreal Biomed	India	1				Yes
Jungbunzlauer	Switzerland	1	Yes			
Kaneka	Japan	1	Yes		Yes	
Kemin	USA	1	Yes			
Lonza	Switzerland	1				Yes
Merck Eprova AG	Germany	1	Yes		Yes	
NattoPharma	Norway	1				Yes
NuLiv Science	USA	1	Yes		Yes	
NutraGenesis	USA	4	Yes			
P.L. Thomas	USA	1				Yes
PhenoFarm	Italy	1				Yes
RIBUS	USA	1	Yes			
Sabinsa Corporation	USA	5	Yes			
SoluBlend Technologies	USA	1	Yes	Yes		
Stepan	Netherlands	1	Yes			
Trace Minerals Research	USA	1	Yes		Yes	
TSI Health Sciences	USA	1	Yes	Yes		
Unibar	USA	1				Yes
Verdure Sciences Trim	USA	1	Yes		Yes	
Totals	**35 companies**	**57**	**24**	**4**	**7**	**11**

The 35 companies that responded but did not provide us with their GRAS determinations fit into the following four categories:

- 13 companies provided us only with assurances that their chemicals were safe and complied with the law.
- 4 companies were willing to share the documentation only if NRDC signed a confidentiality agreement, which we declined to do.
- 7 companies declined to provide the GRAS determination but identified a published toxicology study that supported their analysis without providing the additional information such as exposure calculations and product composition needed to evaluate the safety.
- 11 companies acknowledged the inquiry but did not follow through.

The remaining 107 companies selling 123 chemicals fell into three general categories:

- 50 companies did not appear to market their chemicals for use in food in the United States.[c]
- 54 companies that withdrew notices to the FDA later submitted revised notices and received a final review by the agency confirming product safety.
- 3 companies provided NRDC with a copy of their GRAS determination without requiring confidentiality.

Figure 2 summarizes our findings. Of the 163 companies we reviewed, 56, or 34 percent, appear to rely on undisclosed GRAS determinations.

UNDISCLOSED SAFETY DETERMINATIONS: NOT JUST U.S. COMPANIES

As stated earlier, no other developed country in the world has a system like GRAS for food ingredients.[22] On the basis of each company's website and communications, NRDC identified the home country of the 56 companies with undisclosed GRAS determinations. See Tables 1 and 2. Figure 3 provides the results by region.

Fifty-six percent of the companies are from the United States, and 44 percent are based outside the country. This distribution is similar to what one might see at a typical food expo.

WHY DID COMPANIES FORGO FDA REVIEW?

About 20 companies provided explanations for why they decided not to submit a voluntary notification to the FDA. These can be distilled into the following categories:

- **Concerns about too much FDA transparency.** The most common concern was the FDA's routine posting of GRAS safety determinations to its website. These companies said they were worried that easy access to information about product composition and the manufacturing process would enable competitors to develop identical or similar chemicals and would simplify the competition's own GRAS determinations.
- **Concerns about FDA delays.** Several companies claimed they did not want to wait for the FDA to make a decision, even though the agency explicitly allows the use and marketing of a chemical while a review is under way.

> *"In other words, if a panel of experts reviews data that are not publicly available and subsequently renders an opinion regarding safety, even if the experts are well-recognized, the opinion does not meet the general recognition of safety for GRAS ingredients because the data were not publicly available."*[23]
>
> FDA reviewer of GRAS notice

c Either these chemicals appear to be used only in dietary supplements and not food, or we could not find an active website for the company or the chemical, or the chemicals appear to be marketed only overseas.

- **Desire to keep investment low.** Submitting a GRAS determination to FDA typically means additional work whether by company employees or a consultant doing the analysis. The agency asks many questions that must be answered. Often there are meetings with the agency. We found that almost all of the chemicals NRDC reviewed were also ingredients in dietary supplements and served no essential purpose in food other than to attract consumers' attention. Several companies indicated that a GRAS determination sometimes is done in connection with a test of the food market for a chemical previously used only as a dietary supplement ingredient, thus minimizing the investment in an unproven market by opting out of the FDA review process.
- **Wish to avoid new dietary ingredient review:** The Dietary Supplement Health and Education Act of 1994 (DSHEA) requires manufacturers to notify FDA about dietary ingredients that either were not on the market before 1994 or whose use in food is not GRAS. Several dietary supplement manufacturers appear to be making a GRAS determination to avoid having to notify the FDA under both DSHEA and the Food Additives Amendment of 1958.
- **Misunderstanding of the law:** Some companies apparently did not understand the requirements for a GRAS determination. It appears that they did not realize that the determination must be written, that safety information must be drawn from published scientific studies, or that "generally recognized as safe" means more than obtaining the opinion an employee or consultant. Others apparently believed that an independent panel of experts was required even though the FDA states that no panel is needed.[24] Finally, some companies appeared not to understand the difference between an efficacy study, which determines whether a chemical is effective in addressing a health problem, and a toxicology study, which evaluates whether a chemical may cause harm. The scope of most efficacy studies falls far short of an adequate toxicology study.

Figure 2: Undisclosed vs. Resolved GRAS Determinations

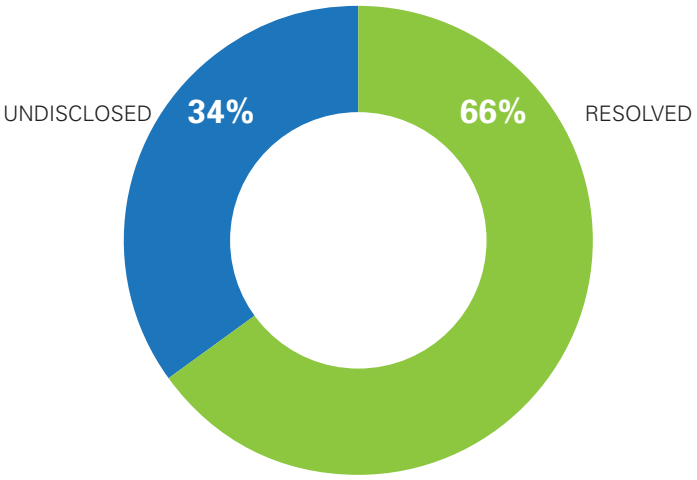
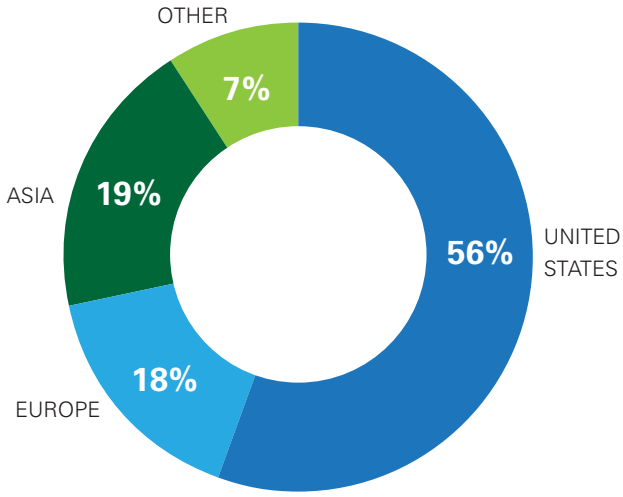


Figure 3: Undisclosed GRAS Determinations by Company's Region



FDA REVIEWS OF NOTICES REVEALED TROUBLING RISKS

As described earlier, companies may voluntarily submit GRAS notices (which contain the GRAS safety determination) to FDA seeking the agency's agreement with their safety determination, and when they do, the agency posts these notices on its website. We reviewed the quality of the industry's notices and identified three, still under review by the FDA as of September 2013 (listed as "pending" on the FDA site), that appeared to be poorly done. They were GRN No. 466 for polyglycerol polyricinoleic acid by McCormick and Co., GRN No. 471 for annatto seed extract by DeltaGold, and GRN No. 474 for Bioperine by Sabinsa Corp.[25,26,27] All three had the same weaknesses: limited toxicology data, poor or inadequate exposure assessment, and lack of consideration of children's exposures. For each we submitted to the FDA detailed comments on the shortcomings of the safety determinations.[28] See www.nrdc.org/food/safety-loophole-for-chemicals-in-food.asp.

If the FDA rejects a GRAS notice, it explains its safety concerns in a letter to the company and publishes the letter on the agency's website. But when a company withdraws a notice and asks FDA to stop further review, the agency issues a letter confirming the withdrawal without publicly explaining any of the concerns that could have prompted the withdrawal. The withdrawal does not prevent the company from continuing to market the product for use in food.

Between 1998 and the end of February 2014, the FDA rejected 17 out of 466 notices submitted to the agency; another 32 are still pending. During that time, 80 notices were withdrawn by the companies. For notices no longer pending, one out of five were either withdrawn or rejected.[29]

After analyzing the poor quality of notices and the number of withdrawn notices, NRDC filed a FOIA request for communications between the FDA and manufacturers for 20 GRAS notifications. We chose notices for chemicals whose use in food we were able to document through a commercial database[30] that provides product information for more than 200,000 food products; and the notices were submitted throughout the length of the program, starting in 1998. Sixteen of these notices were withdrawn, several of them multiple times. Although interested primarily in understanding what concerns raised by FDA prompted manufacturers to ask the agency to stop reviewing the notices, we also included two notices that the agency rejected and two that FDA accepted as sufficient, issuing what is known as a "no questions" letter. To see the FDA's FOIA response, go to www.nrdc.org/food/safety-loophole-for-chemicals-in-food.asp.

The FOIA documents reveal that the FDA does carefully review the notifications and asks tough questions. The agency's reviews often raise serious safety concerns or reveal that the company's scientific analysis is flawed or inconsistent with the law. Often the FDA tells the company that it will reject a notice if it is not voluntarily withdrawn. If rejected, food manufacturers would be more reluctant to buy the product since FDA posts its rejection letter and its reasoning on its website.

The following are examples of four withdrawn GRAS notices and our summary of the back-and-forth communications between the FDA and manufacturers. Despite the safety concerns, these chemicals have been listed as an ingredient in some food products:

Epigallocatechin-3-gallate (EGCG):

A Japanese company declared this chemical to be GRAS for use in beverages including teas, sport drinks, and juices, despite evidence it may cause leukemia in fetuses based on studies using newborn and adult human cells grown on a dish.[31] Moreover, the company did not address a short-term study on rats showing it affected the thyroid, testis, spleen, pituitary, liver, and gastrointestinal tract. The notice did not explain potentially dangerous interactions with sodium nitrite, a common preservative, or with acetaminophen (the active ingredient in Tylenol® and many other over the counter pain-killers).[32] The company withdrew the notice, resubmitted it, but withdrew that one as well.[33] In response to our inquiries, the company assured us it was not marketing the product in the United States. However, two other companies, DSM and Kemin, appear to market chemicals high in EGCG in the United States pursuant to undisclosed GRAS determinations (Table 1). We identified more than 25 food products with EGCG as a named ingredient.

Gamma-amino butyric acid (GABA):

A Japanese company declared this neurotransmitter to be GRAS for use in beverages, chewing gum, coffee, tea, and candy.[34] It did so despite having estimated exposure well in excess of what the company considered safe, relying on unpublished safety studies, providing the specifications in Japanese, and failing to consider existing exposures.[35] The company told NRDC that it withdrew the notice "from a business perspective" and was selling the product in the United States only as an ingredient in a dietary supplement. It also indicated that it would not use the chemical in food without an FDA final review. We identified five food products with GABA as a named ingredient. These products included bottled tea and nutrition bars.

Sweet lupin protein, fiber, and flour:

An Australian firm declared these chemicals to be GRAS for use in baked goods, dairy products, gelatin, meats, and candy, despite concerns that the chemicals would cause allergic reactions in those with peanut allergies.[36] The FDA noted that a warning label for sweet lupin would be insufficient to alert consumers who suffered from peanut allergies.[37] The company did not respond to our inquiries and we could not find evidence that the company was marketing the product in the U.S. However, sweet lupin was a listed ingredient in more than 20 food products, none of which appear to bear any warning to those allergic to peanuts.

Theobromine:

A U.S. firm declared it to be GRAS for use in bread, cereal, beverages, chewing gum, tea, soy milk, gelatin, candy, and yogurt and fruit smoothies, despite having an estimated consumption rate more than five times the safe consumption level reported by the company's consultant.[38] In addition, the manufacturer did not provide convincing explanations for the testicular degeneration in rats and rabbits and delayed bone formation in rats that were seen in animal studies of theobromine.[39] The FDA was especially concerned that the product would be used in baby food.[40] The company did not respond to our inquiries. Although we don't know the provider, theobromine was a named ingredient in more than 20 food products, including isotonic waters, nutrition bars, and diet foods. Fortunately, from what we could tell, none appeared in baby food.

The evidence from these FOIA responses makes it clear: the FDA's review adds value, and many companies' GRAS safety determinations are seriously flawed. The agency should make its concerns publicly available when companies withdraw their notices. Chemicals that, at least in some instances, prompted the FDA to raise safety concerns are used as ingredients in our food supply, and consumers are unprotected from their health effects.

Table 2: Companies with undisclosed GRAS determinations that did not respond to NRDC*

Company	Country	No. of Chemicals
ADM	USA	1
AHD International	USA	1
Ametis JSC	Russia	1
Applied Food Sciences	USA	2
CBC Group	USA	1
Davos Life Sciences	Singapore	1
FutureCeuticals	USA	1
Gencor Pacific	USA	1
Hamari Chemicals	Japan	1
Hanzhong TRG Biotech	China	32
Horizon Science	USA	1
Kyowa Hakko	USA	2
Laurus Labs	India	1
Naturex	Canada	4
Nexira	France	1
NutraMax	China	154
Oxis International	USA	1
Skyherb	China	7
Terry Laboratories	USA	1
Triarco Industries	USA	2
Ventria Bioscience	USA	2
Totals	21 companies	218 chemicals

*In each case, we confirmed that we had either a: 1) confirmation from the company's website that the webform was accepted; or 2) valid email address from website because we did not get a notice from the company's email server that the email had bounced or was not deliverable.

MANY GRAS CHEMICALS BEGAN AS DIETARY SUPPLEMENT INGREDIENTS

Most of the GRAS chemicals NRDC examined were primarily marketed as "active" ingredients in dietary supplements. The availability of the GRAS loophole allows for the expansion of the market for such into conventional foods with claims that they made food "better for you." The chemicals were often extracts of plants or highly purified or synthetic versions of the biologically active chemicals in those extracts, such as antioxidants, which were purported to have possible health benefits.

Since the Dietary Supplement Health and Education Act of 1994[41], when Congress created separate, less rigorous safety standards for dietary supplements under DSHEA, there has been an explosion of these products. Ingredients allowed in dietary supplements are not necessarily safe when used in conventional food.

A product may be a natural extract or a highly purified version of one, but that does not necessarily mean it is safe. In 2014, the FDA recognized the safety threat when it issued guidance regarding substances added to foods, including beverages and dietary supplements.[42] The agency stated:

> *"We have seen a growth in the marketplace of beverages and other conventional foods that contain novel substances, such as added botanical ingredients or their extracts. Some of these substances have not previously been used in conventional foods and may be unapproved food additives. Other substances that have been present in the food supply for many years are now being added to beverages and other conventional foods at levels in excess of their traditional use levels, or in new beverages or other conventional foods. This trend raises questions regarding whether these new uses are unapproved food additive uses."*[43]

It is likely that had the FDA reviewed the undisclosed GRAS determinations, it would have found some to be unapproved food additives.

THE SYSTEM IS BROKEN AND PLAGUED WITH CONFLICTS OF INTEREST

When the FDA reviewed GRAS determinations made by manufacturers, the agency found flaws with one in five, based on the number of notices rejected or withdrawn prior to a final decision.[44] These notices presumably were those in which the manufacturer's had the most confidence, since the manufacturers voluntarily submitted them for agency scrutiny.

Food manufacturers are ultimately responsible for the safety of the food they make. However, in today's highly competitive global marketplace, there are strong economic incentives to minimize expenditures, which may lead to insufficiently-justified decisions. Our understanding of the health effects of many of the more than 10,000 chemicals allowed in food is far from complete, and as the number grows over time, concerns grow as well. For example, some manufacturers still consider *trans* fats to be GRAS despite the FDA's concluding that it causes eight deaths a day in the United States and that if it were banned from food, our country would realize more than $117 billion in health benefits including reduced healthcare costs over 20 years.[45]

Here is another issue of serious concern. For years, companies have used their own employees or hired consultants to evaluate their chemicals' safety and then relied on such undisclosed safety determinations to market their products for use in food. This raises serious conflict-of-interest concerns because a company's financial benefit from selling a particular product can bias its employees' or contractors' judgment.[46] The lack of independent review in GRAS determinations compromises the integrity of the process and calls into question whether it can effectively ensure the safety of the food supply.[47]

The FDA has acknowledged that a company's potential legal liability and its interest in protecting its brand are insufficient to ensure that food is safe.[48] In 2013 the agency said, "Because the demand for many manufactured or processed foods may not be sufficiently affected by safety considerations, incentives to invest in safety measures from farm to fork is diminished. Consequently, the market may not provide the incentives necessary for optimal food safety."[49]

"Even in cases where consumers are aware that their illness was contracted from a specific food," the FDA explained, "it is often difficult to determine who is ultimately responsible for their illness, since the particular source of contamination is not known in many circumstances."[50] It concluded that "it is unlikely that the existence of brands in the food sector creates the optimal level of safety for society."[51]

As the Institute of Medicine explained in the context of medical safety, conflicts of interest can result in bad decisions.[52] Similarly, undisclosed safety determinations affecting the food that Americans eat may be undermining public health. Without FDA and public scrutiny—as Congress intended that there be—we cannot be confident in the safety of chemicals added to food.

CONCLUSIONS

A chemical additive cannot be "generally recognized as safe" if its identity, chemical composition, and safety determination are not publicly disclosed. Congress never intended that almost all new food chemicals would pass through the GRAS loophole without formal agency review and approval. The law places responsibility on FDA to ensure that food additive petitions are submitted for additives without general recognition of safety and to ensure that manufacturers' GRAS determinations are properly made. If the FDA does not know the identity of these chemicals and does not have documentation showing that their uses in food are safe, it cannot not do its job.

In an increasingly global marketplace where many additives and foods are imported into the United States, this loophole presents an unsettling situation that undermines public confidence in the safety of food and calls into question whether the FDA is performing its duty to protect public health. Until conflicts of interest are minimized and safety decisions are subject to mandatory FDA review, the safety of chemicals in food will depend largely on the integrity and competence of food manufacturers. That is not in the public's best interest, because manufacturers have a financial incentive that may bias their judgment about an additive's safety.

When consumers buy dietary supplements, they make a choice to consume chemicals that the FDA has not reviewed for safety. Indeed, under the law, consumers must be told that FDA has not reviewed the health claims made for ingredients in dietary supplements. As a result, dietary supplements carry labels disclosing that they have not been reviewed for safety by the FDA. However, when buying food, consumers can't make informed choices because they don't know which ones contain reviewed chemicals or which contain substances not reviewed by the FDA for safety. There are no warning labels. There is no disclosure. As a consequence, they may unknowingly be putting their health at risk. The current processes allowing this to occur should be addressed and changed to better protect the health of the American public.

NRDC'S RECOMMENDATIONS

The problems identified in this report are rooted in a law adopted more than a half century ago. Ultimately, Congress needs to fix these problems. Until it does, the FDA should implement the recommendations made by the GAO in 2010 including strictly limiting conflicts of interests and requiring that the FDA be informed of GRAS determinations so it can confirm that the chemical's use in food is generally recognized as safe. The agency should also make its concerns with all notices it reviews, even those that are withdrawn, publicly available.

In the meantime, consumers should demand that their grocery stores and their favorite brands sell only food products with ingredients that the FDA has found safe, and call on the FDA and Congress to make the necessary changes to better ensure that food consumed in the U.S. is safe.

ENDNOTES

1 Thomas G. Neltner et al., "Navigating the U.S. Food Additive Regulatory Program," *Comprehensive Reviews in Food Science and Food Safety* 10 (2011), p. 342.

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3 21 U.S.C. § 321(s) and § 348.

4 Pub. L. No. 85-929, 72 Stat. 1784 (1958).

5 21 C.F.R. § 170.3(i).

6 21 U.S.C. § 348. Fred H. Degnan, *FDA's Creative Application of the Law*, Food Drug Law Institute, 2000, p. 25.

7 Degnan, p. 22.

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9 NRDC, GRN No. 59 FDA Response to FOIA, 2014, p. 271, www.nrdc.org/food/files/chemicals-in-food-FOIA-59.pdf.

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14 21 C.F.R. § 170.35.

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24 Kahl, p. 5.

25 FDA, GRAS Notice Inventory, GRN No. 466. www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices. The FDA issued a "no questions" letter before the NRDC submitted its comments.

26 Ibid, GRN No. 471. It was pending as of February 28, 2014.

27 Ibid, GRN No. 474. It was withdrawn before the NRDC submitted its comments.

28 NRDC, Comments on GRN No. 466, 2013, www.nrdc.org/food/files/chemicals-in-food-GRN-466.pdf and NRDC, Comments on GRN No. 471, 2013, www.nrdc.org/food/files/chemicals-in-food-GRN-471.pdf and NRDC, Comments on GRN No. 474, 2013, www.nrdc.org/food/files/chemicals-in-food-GRN-474.pdf.

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30 See www.gladson.com. March 15, 2013 version

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ATTACHMENT 21

The Washington Post

Federal Insider

Are secret, dangerous ingredients in your food?

By Kimberly Kindy April 7, 2014

Food manufacturers are routinely exploiting a “legal loophole” that allows them to use new chemicals in their products, based on their own safety studies, without ever notifying the Food and Drug Administration, according to a new report by an environmental and consumer advocacy group.

Natural Resources Defense Council identified 56 companies that were marketing products using 275 chemicals that the company’s hired experts decided met federal safety standards, known as Generally Recognized as Safe (GRAS). However, the science behind those safety findings and the use of the chemicals was disclosed to the FDA in only six instances. The New York-based NRDC called its report “Generally Recognized as Secret” and said the lack of transparency with the GRAS process is a public health threat.

“If you don’t know when (an additive) is being used, how can you determine if it’s safe?” said Thomas Neltner, a chemical engineer and co-author of the study that was presented Monday at a Grocery Manufacturers Association’s Science Forum at Washington.

In a prepared statement, the GMA defended the GRAS process, saying, “It is a very thorough and comprehensive process that has, under the current law provided FDA with authority to challenge the improper marketing of an ingredient as GRAS, and if necessary, act to remove products containing that ingredient from the food supply.”

The FDA said that although the law allows for food manufacturers to make their own safety determinations, the agency “encourages companies to consult with the agency when developing new ingredients.” Ultimately, the FDA said, manufacturers “are responsible for ensuring that their food products are safe and lawful.”

NRDC said that Food Additives Amendment of 1958 was enacted, the GRAS process was meant to apply to innocuous additives like vinegar. Instead, it is commonly used for chemicals that are potentially dangerous and have never before been in the American food supply. For example, until recently, artificial transfats were considered GRAS but the FDA has now deemed them dangerous, saying they cause as many as 7,000 deaths from heart disease each year.

The organization said its findings are “likely the tip of the iceberg,” since the scientific work and GRAS determinations are not publicly disclosed and therefore difficult to track down. The organization spent more than a year reviewing trade journals and talking to food additive consultants to identify the 56 companies that frequently make their own safety determinations.

The FDA’s food additive process allows companies to take several paths to determine the safety of new chemicals or other ingredients.

The most transparent and rigorous path involves companies submitting a food additive petition – along with the science behind why they think the ingredient is safe — to the FDA in an effort to gain formal approval from the agency. Companies use the FDA approvals to promote the safety of their products.

The other, non-public path that NRDC examined allows companies to determine GRAS status on their own without notifying the FDA.

A third path allows companies to voluntarily submit their own GRAS determinations for FDA review and sign off, but they may withdraw the petition if the agency is worried about the safety of the additive. The agency announces the withdrawal but does not disclose whether it had safety concerns. The company may then go ahead and use its own GRAS determination to use the additive in products anyway. The NRDC found that one in every five GRAS petitions were either rejected by the FDA or the company voluntarily withdrew their petition.

NRDC’s report also calls on the FDA to petition Congress for a new law that would require manufacturers to submit their safety determinations to the agency for review and approval. The council said it is encouraging consumers to “demand” that their grocery stores and their favorite brands sell only food products with ingredients that the FDA has found to be safe.

At Monday’s event, the Grocery Manufacturers Association also announced a new food additive research center it has helped create at Michigan State University, which will be called the Center for Research on Ingredient Safety (CRIS). GMA’s chief science officer, Leon Bruner, said the center will operate independent of the association and will review the safety of ingredients, train future food toxicologists and serve as an “independent and credible source” for the public, news organizations and the industry.

Kimberly Kindy is a national investigative reporter at The Washington Post. Follow @kimberlykindy

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ATTACHMENT 22

E&E NEWS

BRISTOL BAY

'Homework assignment' — how Pebble lobbied Trump's EPA

Kevin Bogardus and Dylan Brown, E&E News reporters

Greenwire: Thursday, June 8, 2017

The backers of the controversial Pebble mine planned for Alaska's Bristol Bay lobbied U.S. EPA to reverse its decision on the mining project. Robert Glenn Ketchum/Natural Resources Defense Council

Developers of a controversial Alaskan mine set out early to lobby President Trump's U.S. EPA to reverse restrictions the Obama administration had proposed putting on the project.

Peter Robertson, a top lobbyist for Pebble LP — the developer of the Pebble mine in Bristol Bay, Alaska — emailed and met with a senior EPA official to discuss the project, according to records released in response to a Freedom of Information Act request by the Natural Resources Defense Council. The documents illuminate that the latest push in Pebble's decadelong lobbying campaign bore fruit, as the company and EPA reached a deal last month to allow the project to enter permitting.

Two days before the Senate confirmed Scott Pruitt as EPA administrator in February, Robertson — who also served as EPA chief of staff under then-agency head Carol Browner during the Clinton administration — reached out to David Schnare at EPA, asking to meet in person to discuss the mining project.

Robertson **said in an email** that EPA's effort, through its Pacific Northwest Region 10 office, that effectively blocked the mine was "unprecedented and fundamentally unfair."

In 2014, Region 10, which oversees Alaska, proposed Clean Water Act restrictions on large-scale mining in Bristol Bay (***Greenwire***, May 17). Alaska Native groups, conservationists and the commercial fishing industry praised EPA for protecting the region's world-renowned salmon fishery.

Peter Robertson EPA Alumni

"We are only looking for the same due process that 60,000 other permit applicants get each year," Robertson said, noting that "there is a significantly long history of this matter (including our litigation against the Agency), and I would appreciate the opportunity to discuss it with you and seek your guidance and assistance on our efforts to work through these issues with the Agency.

"Do you have time for me to meet with you in the near future?" Robertson asked.

Schnare **responded** the next day, saying he was open to meeting with the Pebble mine lobbyist.

"I am aware of the problem in general but do not have specifics. Can you bring with you a timeline of events and a status on the legal actions? The preemptive strike by the last administration was indeed unprecedented and I don't want to see it become a precedent, particularly because it is a violation of Pebble's due process rights," Schnare said.

"In any case, I need to get this set up for the Administrator, which means I need the full background and a specific proposal on what we can and should do. Without meaning to be flip,

that's your homework assignment," Schnare added.

The two then arranged to meet in person the following week, according to the emails. A day after the Feb. 22 meeting date, Robertson **emailed** Schnare to thank him and pass on several websites and documents — including a **letter** from House Science, Space and Technology Chairman Lamar Smith (R-Texas) asking EPA to let the mining project move forward.

"If you have questions after speaking with Region 10, I would really appreciate the opportunity to respond to them," Robertson said.

The next week, Robertson again emailed Schnare, passing along a **letter** from Pebble to Rep. Eddie Bernice Johnson (D-Texas), the Science panel's ranking member, taking issue with the congresswoman's criticism of the project (***Greenwire***, Feb. 27).

"What I really wanted to talk about though, is the substance of it," Robertson **said**.

'Tip of the FOIA iceberg'

A Region 10 official said EPA headquarters would be declining to comment on this story.

In an email responding to questions about Pebble's lobbying of EPA, Robertson said: "We have met with a range of people at EPA — during this administration and the prior administration — to discuss the many problems with their precedent-setting preemptive actions against us.

"Our efforts have been targeted towards ensuring that EPA's leaders are well informed about all relevant issues regarding our project. Discussions regarding settlement, as you would expect, have largely been handled by our lawyers."

Taryn Kiekow Heimer, a senior policy analyst at NRDC who requested the records via FOIA, criticized Pebble's discussions with EPA over the mining project, calling it "a shameless giveaway to industry" to let the permitting process move forward.

"After years of belly-aching about fairness, it is simply unbelievable that Pebble immediately seized the opportunity to reach a secretive, backroom deal with the Trump EPA," she said in an email. "Trump's EPA went from not knowing any 'specifics' about the mine to cutting a deal with Pebble that greenlights the mine into permitting."

Schnare, the EPA official who met with Robertson, was a member of Trump's transition team and later the "beachhead" team for the agency. He had previously spent 33 years at EPA, including working as an attorney in the agency's enforcement office, before returning to EPA this year.

At the Energy and Environment Legal Institute, Schnare was a vocal critic of EPA under the Obama administration. He expected to stay on at EPA in a top position but resigned from the agency by mid-March after he made allegations of wrongdoing (***Greenwire***, March 16).

In an interview with E&E News, Schnare remembered meeting with Robertson and discussing the mining project with other EPA beachhead team members.

Schnare said after he was briefed by Pebble, he sought and received a briefing from EPA staff. Then, Schnare said, he took the information to Pruitt

"I never gave anything to Pruitt. I did brief him," Schnare said.

Schnare said he wanted to make sure that all sides and arguments surrounding the issue were known within EPA.

"There was nothing offered up by Peter Robertson that the agency didn't already know," Schnare said. "My approach has been to hear from both sides."

Schnare also said "there was this whole precedence issue" with the Pebble mine.

"Do you kill a project without due process?" Schnare said. "Due process is something the public deserves."

NRDC's Kiekow Heimer questioned EPA's decisionmaking process that led to the settlement, saying the agency lacked "a balanced perspective since there was no effort, as far as I know, to reach out to any of the stakeholders except Pebble."

More information may be forthcoming on Pebble's lobbying campaign directed at Trump's EPA. Kiekow Heimer said she expected the agency to produce two more rounds of documents in response to her request.

"This is just the tip of the FOIA iceberg," she said.

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ATTACHMENT 23

The New York Times

E.P.A. Readies Plan to Weaken Rules That Require Cars to Be Cleaner

By Hiroko Tabuchi, Brad Plumer and Coral Davenport

April 27, 2018

The Trump administration has drafted a new set of regulations on planet-warming emissions from cars and light trucks that would dramatically weaken Obama-era standards. The proposal, if implemented, would also set up a legal clash between the federal government and California by challenging the state's authority to set its own, stricter, air pollution rules.

Details of the proposal, which is being jointly drafted by the Environmental Protection Agency and the Transportation Department and is expected to be sent to the White House for approval in coming days, were described to The New York Times by a federal official who had seen them but was not authorized to discuss the matter.

The proposal follows an announcement this month by the E.P.A. administrator, Scott Pruitt, that the Trump administration intended to weaken the stringent vehicle fuel economy standards set by the Obama administration that aimed to roughly double the average fuel economy of new cars, S.U.V.s and light trucks by 2025.

The E.P.A. declined to comment on the emissions proposal, which could still change before being made public.

In the draft, the agencies lay out eight different options for revising the Obama-era standards. The preferred course of action would freeze fuel-economy standards at 2020 levels for both cars and light trucks, greatly slowing progress in reducing auto emissions.

The proposal also challenges California's authority to impose its own vehicle standards.

Currently, California has a waiver under the Clean Air Act to impose its own, stricter, air pollution regulations on cars and trucks to deal with problems like smog. But the administration's draft proposal argues that California cannot use this waiver to set standards on greenhouse gas emissions from vehicles because that would be tantamount to regulating fuel economy, which states are forbidden from doing under a 1975 law.

The auto industry has previously tried to challenge California's greenhouse gas standards for vehicles on these grounds, but federal courts have so far rejected their arguments. Legal experts have said that, as long as California is regulating the pollutants that come out of tailpipes and not

directly determining fuel economy standards, the state is on solid legal ground.

The Trump administration has also signaled that it would consider rescinding California's waiver altogether, although the draft proposal does not mention this. On Thursday, Mr. Pruitt told Congress that the agency was still in "active discussions" with California and had no plans at the present to revoke the waiver.

In recent months, automakers have become increasingly nervous about the Trump administration's collision course with California. A group of automakers has requested a direct meeting with President Trump to urge the administration to avert a legal clash with California, which could plunge the auto industry into regulatory chaos, according to two people with knowledge of the automakers' plans. A spokeswoman for the Alliance of Automobile Manufacturers was not immediately available for comment.

For its part, California has declared it will stick with the stricter, Obama-era regulations, a decision that could effectively split the United States into two auto markets and set up a messy legal battle.

Stanley Young, a spokesman for the state's clean air regulator, the California Air Resources Board, said the agency was not aware of any official proposal. But if true, "this would harm people's health, boost greenhouse gas pollution and force drivers to pay more money at the pump for years."

"It would also severely disrupt the U.S. auto industry, compromising its ability to succeed in a highly competitive global market that increasingly values innovative and efficient technologies," Mr. Young said.

A rollback of the rules, which were designed to reduce emissions of greenhouse gases, would blunt one of the single biggest steps any government has taken to tackle climate change.

Adopted in 2012, the Obama-era standards would have required new cars and trucks to average more than 50 miles per gallon by 2025 if automakers complied solely by improving the fuel economy of their engines. (Because automakers can get credit for actions like using less-polluting refrigerants in air-conditioning units, the actual fuel economy of new vehicles is expected to be lower.)

But under the draft proposal's preferred outcome, fuel economy standards would be frozen after 2020, keeping the fuel economy target closer to 40 miles a gallon through 2025.

Other possible approaches in the draft proposal involve progressively increasing fuel economy by between 0.5 percent and 2 percent a year for cars, and from 0.5 percent to 3 percent for light trucks.

The E.P.A. and Transportation Department are expected to send their proposal to the White House's Office of Management and Budget in the coming days for review. Once the proposal is reviewed and published in the federal register, it will have to undergo a public comment period and may see further changes before being finalized.

Because automakers already have the technology in place for their 2020 models, freezing those standards would be tantamount to ceasing to regulate fuel economy improvements altogether, said Ann E. Carlson, a professor of environmental law at the University of California, Los Angeles.

"This is essentially saying to automakers: Keep doing what you've already been doing," she said. "It's like saying: We are not going to regulate you anymore. You're already geared up to meet the standards and we're finished."

Hiroko Tabuchi reported from New York, and Brad Plumer and Coral Davenport from Washington.

Hiroko Tabuchi is a climate reporter. She joined The Times in 2008, and was part of the team awarded the 2013 Pulitzer Prize for Explanatory Reporting. She previously wrote about Japanese economics, business and technology from Tokyo. @HirokoTabuchi • Facebook

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A version of this article appears in print on April 27, 2018, on Page A15 of the New York edition with the headline: Plan to Loosen Emission Limits Disputes California's Right to Set Its Own

ATTACHMENT 24

THE LEADER IN ENERGY AND ENVIRONMENT NEWS

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WHITE HOUSE

OMB changes details of fuel efficiency proposal

Maxine Joselow, E&E News reporter

Published: Monday, June 4, 2018

The Office of Management and Budget has changed the dates on a fuel efficiency proposal on the site Reginfo.gov. Reginfo.gov

The White House has altered key details of a proposal for revised clean car rules, an under-the-radar regulatory move that seems to confirm reports of an assertive rollback.

The White House Office of Management and Budget appears to have changed the title and dates in the proposal from EPA and the National Highway Traffic Safety Administration on Friday.

The proposal is now **listed** on Reginfo.gov as "2021-2026 Model Year Corporate Average Fuel Economy Standards and Light-Duty Vehicle Greenhouse Gas Emissions Standards."

Previously, the proposal was listed on the site and in the administration's spring regulatory plan as "Passenger Car and Light Truck Corporate Average Fuel Economy Standards MYs 2022-2025."

OMB has been reviewing the proposal, to be made available for public comment, since the two agencies submitted it Thursday (***Greenwire***, May 31). Reginfo.gov serves as a clearinghouse on the status of rulemakings across government.

"The Department of Transportation updated the title in our system to accurately reflect the title of the proposed rule. This is not uncommon to correct a mistake or error upon first entry," a spokesman for the budget office said on background.

But sources said the change could speak to the substance of the proposal.

EPA and NHTSA have been tight-lipped about the proposal's substance while it undergoes standard interagency review. An EPA spokeswoman previously told E&E News, "As clearly laid out in EPA's April 2018 Final Determination, EPA has worked with NHTSA to develop a joint proposed rule and that rule has been sent to OMB for interagency review. Until this process is complete, we will not provide comment on rules undergoing interagency review."

Sources familiar with the matter, however, **told** Reuters that the proposal will outline a series of alternatives, and the preferred option will be to freeze fuel economy targets at 2020 levels through 2026.

Paul Billings, national senior vice president for advocacy with the American Lung Association, said the changes on Reginfo.gov appear to confirm those reports.

"I think it does signal, perhaps even confirm, the rumors and the leaks about this being a very broad rollback," said Billings, who noticed the new details over the weekend.

This isn't the first time observers have noticed changes on Reginfo.gov. In April, OMB altered an official timeline to show that a required review of an EPA science rule was finished one day before EPA Administrator Scott Pruitt signed it (***Greenwire***, April 27).

"There are questions about the reliability and coherence from Reginfo.gov," Billings said. "With the 'censoring science' proposal, they changed dates and backdated a completion. Here, they're changing the title of the proposal."

He added, "What's going on there? This is supposed to be a process that includes interagency review and allows public participation. It seems that at least potentially, there is something that is nefarious that is going on with that process."

EPA and NHTSA didn't respond to requests for comment this morning.

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ATTACHMENT 25

The Washington Post

Health & Science

EPA to roll back car emissions standards, handing automakers a big win

by Juliet Eilperin and Brady Dennis April 2 Email the author

Environmental Protection Agency Administrator Scott Pruitt announced Monday that he would revoke Obama-era standards requiring cars and light trucks sold in the United States to average more than 50 miles per gallon by 2025, a move that could change the composition of the nation's auto fleet for years.

The push to rewrite the first carbon limits on car s and SUVs, which came out of an agreement among federal officials, automakers and the state of California, is sure to spark major political and legal battles.

California has authority under the Clean Air Act to set its own emissions limits, and it has threatened to sue if its waiver is revoked and it is blocked from imposing stricter targets. Such a fight has broad implications, because 12 other states, representing more than a third of the country's auto market, follow California's standards.

Pruitt's decision reflects the power of the auto industry, which asked him to revisit the Obama administration's review of the model years 2022-2025 fuel-efficiency targets just days after he took office. President Trump told autoworkers in Detroit last year that he was determined to roll back the emissions rules as part of a bigger effort to jump-start the nation's car industry.

"The Obama administration's determination was wrong," Pruitt said in a statement. "Obama's EPA cut the Midterm Evaluation process short with politically charged expediency, made assumptions about the standards that didn't comport with reality, and set the standards too high."

Pruitt did not specify what limits would be put in place, saying the EPA and the National Highway Traffic Safety Administration would establish a standard that "allows auto manufacturers to make cars that people both want and can afford — while still expanding environmental and safety benefits of newer cars." The agency said he is still considering the status of California's waiver.

Officials in that state immediately excoriated the decision.

“This is a politically motivated effort to weaken clean vehicle standards with no documentation, evidence or law to back up that decision,” Mary Nichols, head of the California Air Resources Board, said in a statement. She argued that the move would “demolish” the nation’s shift toward cleaner cars and that “EPA’s action, if implemented, will worsen people’s health with degraded air quality and undermine regulatory certainty for automakers.”

Nichols also hinted at a potential legal fight to come.

“This decision takes the U.S. auto industry backward, and we will vigorously defend the existing clean vehicle standards and fight to preserve one national clean vehicle program,” she said. The EPA’s decision “changes nothing in California and the 12 other states with clean-car rules that reduce emissions and improve gas mileage — those rules remain in place.”

The efficiency gains that the U.S. auto fleet has made in recent decades have slowed since 2013, as gas prices dipped and the sale of pickup trucks and SUVs accelerated. In the document Pruitt signed Monday, he said the EPA had been “optimistic in its assumptions and projections” about the availability of technology to meet the standards and the agency recently had received substantial input from automakers that they needed to be scaled back.

He suggested that if cleaner vehicles are too expensive, consumers will hold onto older cars, thereby lowering the overall efficiency of cars on the road.

Peter Welch, president and chief executive of the National Automobile Dealers Association, said in a statement Monday that while the group supports “continuous improvements” in reducing vehicle emissions, “Standards alone — whatever they are — won’t do the trick.”

The Alliance of Automobile Manufacturers, whose members produce 70 percent of the cars and light trucks sold in the United States, endorsed the shift. The group estimates that it would be more realistic to require the fleet to reach a miles-per-gallon target in the high 40s by 2025.

The U.S. fleet averaged 31.8 mpg for model year 2017, according to federal figures.

Alliance spokeswoman Gloria Bergquist said in an email that her members "support the administration for pursuing a data-driven effort and a single national program as it works to finalize future standards. We appreciate that the administration is working to find a way to both increase fuel economy standards and keep new vehicles affordable to more Americans."

But two auto companies, Ford and Honda, recently urged the government to maintain the current requirements but give manufacturers additional flexibility.

Dan Becker, director of the Safe Climate Campaign, projected that retaining the Obama rule would cut carbon dioxide emissions by 6 billion tons and save 12 billion barrels of oil over the lifetime of vehicles complying with these standards. "Even though automakers are pushing gas-guzzling pickups and SUVs rather than more efficient cars, it's still the biggest step any nation has ever taken to cut global warming pollution and save oil," he said.

Two of Pruitt's predecessors were harshly critical.

"All they care about is undoing everything the prior administration did, and they'll use any excuse for doing that. They don't even have the industry itself asking for this," said Gina McCarthy, EPA administrator under President Barack Obama and now director of Harvard's Center for Health and the Global Environment.

McCarthy said that the standards set during the Obama era were based on extensive negotiations with states and the federal government, as well as the auto industry. "The decision I made was based on real information," while Pruitt's decision seemed to have no factual basis, she said.

And former EPA administrator Carol M. Browner, who helped forge the initial carbon thresholds for cars and light trucks in 2009 while serving in the Obama White House, took issue with Pruitt's allegation that officials in California are somehow at fault, saying "this idea that California is dictating or arbitrating for the rest of the country is not accurate."

Rather, Browner said, federal and state officials in past administrations worked to reach a compromise that gave certainty to automakers while moving the nation to embrace more fuel-efficient vehicles.

"There's an opportunity for us to lead the global market in cleaner, more efficient cars," she said. "But [Trump officials] are simply going to walk away from that opportunity."

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Read more:

Some automakers have second thoughts on rolling back fuel efficiency rules

Pruitt says California is 'not the arbiter" of national tailpipe standards

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569 Comments

Juliet Eilperin is The Washington Post's senior national affairs correspondent, covering how the new administration is transforming a range of U.S. policies and the federal government itself. She is the author of two books — one on sharks and another on Congress, not to be confused with each other — and has worked for The Post since 1998. Follow @eilperin

Brady Dennis is a national reporter for The Washington Post, focusing on the environment and public health issues. He previously spent years covering the nation's economy. Dennis was a finalist for the 2009 Pulitzer Prize for a series of explanatory stories about the global financial crisis. Follow @brady_dennis

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ATTACHMENT 26

Department of Energy
Washington, DC 20585

February 10, 2011

Mr. Joshua Berman
Natural Resources Defense Council
1200 New York Avenue, NW, Suite 400
Washington, DC 20005

Re: HQ-2011-00601-F

Dear Mr. Berman:

This is an interim response to the request for information that you sent to the Department of Energy (DOE) under the Freedom of Information Act (FOIA), 5 U.S.C. 552. You asked for records that reflect communications between the DOE and the Federal Housing Finance Agency and/or the Office of the Comptroller of the Currency regarding Property Assessed Clean Energy (PACE) energy efficiency retrofit programs, and any responses or attachments.

The request has been assigned to the Office of Energy Efficiency and Renewable Energy to conduct a search of its files for responsive records. Upon completion of the search and the review of any records located, you will be provided a response.

In your letter, you agreed to pay up to $100.00 for fees associated with the processing of the request. You also requested a waiver of processing fees, and stated that disclosure of the information will help to inform the public about the DOE's change of position regarding the PACE program.

For purposes of assessment of fees, you have been categorized under the DOE regulation at Title 10, Code of Federal Regulations, Section 1004.9(b)(3), as a "news media" requester. Requesters in this category are charged fees for duplication only and are provided 100 pages at no cost.

I have reviewed the information that you provided with your letter to support the request for a fee waiver or reduction and determined that the information satisfies the criteria considered for a waiver of fees. A waiver, therefore, is appropriate for fees that may be incurred because the subject of the request relates to a government activity, and information about the activity could lead to greater public understanding about the matter.

The above referenced number has been assigned to the request and you should refer to it in correspondence with the DOE about this matter. If you have questions about processing the request, please contact Ms. Ruth Mosby in the Office of Energy Efficiency and Renewable Energy at EE-12/Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585. She also can be contacted on (202) 586-8757.

I appreciate the opportunity to assist you. You may contact Ms. Joan Ogbazghi in this office on (202) 586-3595 with any questions about this letter.

Sincerely,

Joan Ogbazghi
for Alexander C. Morris
FOIA Officer
Office of Information Resources

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